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Increasing contraception use with mobile phone-based interventions

Chris Smith

**Thesis submitted in accordance with the requirements for the
degree of Doctor of Philosophy, University of London**

2017

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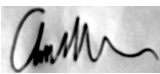
Declaration

I, Chris Smith, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indication in the thesis.

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Abstract

Background

Interventions delivered by mobile phone have been demonstrated to be effective in other health areas. This thesis focuses on interventions delivered by mobile phone to increase contraception use.

Methods

This thesis comprises a systematic review, development and evaluation of the MOBILE Technology for Improved Family Planning (MOTIF) intervention to support post-abortion contraception in Cambodia with randomised controlled trial, and a mixed methods process evaluation.

Results

The systematic review identified five trials, two of which increased self-reported contraception use, one in the USA and the MOTIF trial in Cambodia (four-month data only). A meta-analysis was not possible due to differing interventions and outcome measures.

Development of the MOTIF intervention involved literature reviews on determinants of contraceptive use, interviews and focus groups with women seeking abortion services in Cambodia. The intervention comprised six interactive voice messages with counsellor support depending on the response to the message.

The intervention was associated with increased self-reported use of effective contraception at four months post-abortion (64% vs. 46%; Risk Ratio (RR): 1.39; 95% Confidence Interval (CI): 1.17–1.66) but not at 12 months (50% versus 43%; RR: 1.16; 95% CI: 0.92–1.47). Long-acting contraception use (intrauterine device, implant,

permanent method) was increased at four and 12 months. There was no significant difference in repeat pregnancies or abortions at four or 12 months.

The intervention effect was primarily due to increased initiation of long-acting contraception. The majority of women were positive about the intervention which provided support for physical and emotional issues in addition to contraception use. The intervention could be implemented in current form, however cost-effectiveness data is lacking. The intervention could potentially be improved and further evaluated.

Conclusions

Interventions delivered by mobile phone can increase contraception use, but the evidence to date is mixed. Further trials of interventions delivered by mobile phone to increase contraception use are required.

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Abbreviations

ART	Anti-retroviral therapy
BCT	Behaviour change technique
CBG	Corticosteroid Binding Globulin
CDHS	Cambodia Demographic and Health Survey
CENTRAL	Cochrane Central Register of Controlled Trials
CF	Caroline Free
CI	Confidence Interval
COCP	Combined Oral Contraceptive Pill
CS	Chris Smith
CYP	Couple Year of Protection
DHS	Demographic and Health Survey
DMPA	Depot medroxyprogesterone acetate
EE2	Ethinylestradiol
ELISA	Enzyme-linked immunosorbent assay
EMD	Electronic Monitoring Device
FDG	Focus Group Discussion
FP	Family planning
GIS	Geographic Information System
GRADE	Grades of Recommendation, Assessment, Development and Evaluation
HIV	Human Immunodeficiency Virus
HR	Hazard Ratio
ICER	Incremental Cost Effectiveness Ratio
ID	Identification
ITT	Intention to treat
IUD	Intra-uterine device
IUS	Intra-uterine system
JG	Judy Gold
KK	Khemrin Khut
LILACS	Latin American Caribbean Health Sciences Literature
LS	Ly Sokhey
LARC	Long-acting reversible contraception
LTFU	Loss to follow-up
LSHTM	London School of Hygiene and Tropical Medicine
m4RH	Mobile 4 Reproductive Health
MAMA	Mobile Alliance for Maternal Action
MAR	Missing at random
MD	Mean Difference
MOTIF	MOBILE Technology for Improved Family Planning
MRC	Medical Research Council

MSI	Marie Stopes International
MSIC	Marie Stopes International Cambodia
MI	Multiple imputation
MICE	Multiple impression by chained equations
MJP	Maddox Jolie-Pitt
NECHR	National Ethics Committee for Health Research (Cambodia)
NHS	National Health Service (UK)
NICE	National Institute for Health and Clinical Excellence
NMAR	Not missing at random
NMCHC	National Maternal Child Health Centre (Cambodia)
OC	Oral Contraceptive
OR	Odds Ratio
PAC	Post-abortion care
PAFP	Post-abortion family planning
PE	Phil Edwards
POP	Progestogen-only pill
POPLINE	Population Information Online
RA	Research Assistant
RCT	Randomised control trial
RR	Risk Ratio
RTA	Road traffic accident
RW	Ruby Warnock
SIM	Subscriber Identification Module
SMS	Short message service
SOC	Standard of care
SOP	Standard Operating Procedure
TBG	Thyroxine Binding Globulin
TFR	Total Fertility Rate
TN/TDN	Thoai Ngo
TR	Tung Rathavy
UK	United Kingdom
UNICEF	United Nations Children's Fund
USA	United States of America
USD	United States Dollar
UV	Uk Vannak
WHO	World Health Organization

1. Study background

This PhD thesis examines interventions delivered by mobile phone to increase use of contraception. The main body of work relates to the Mobile Technology for Improved Family Planning (MOTIF) trial; a randomised controlled trial (RCT) of a mobile phone-based intervention to support post-abortion family planning (PAFP) in Cambodia. This chapter reviews literature on contraception and interventions delivered by mobile phone with a particular focus on the Cambodian context, and outlines the aims and objectives of this thesis.

1.1 Global contraceptive trends and determinants

Contraception, abortion and post-abortion family planning (PAFP)

Contraception - methods or devices to prevent pregnancy - has significant benefits for both women's and child health. The use of contraception prevents unintended pregnancies, reduces the number of abortions and maternal deaths, and can improve perinatal outcomes and child survival by widening the interval between successive pregnancies.(1) Reducing unintended pregnancies can result in substantial social and economic benefits such as improved educational and employment opportunities for women leading to increasing family savings and economic growth.(2)

Contraception can be classified in different ways. Contraception can be categorised as either *modern* (for example sub-dermal implant, injectables) or *traditional* (for example rhythm/periodic abstinence, withdrawal).(3) Furthermore, distinctions can be made between hormonal or non-hormonal methods (e.g. sub-dermal implant vs. condom) or by duration of action (for example short, long-acting, permanent methods, or Long-Acting Reversible Methods (LARC), a term commonly used in the United Kingdom).(4) One drawback of categorising according to duration of action is that the

definition of a method can vary in different locations, for example the National Institute for Health and Clinical Excellence (NICE) considers LARC methods those that require administering less than once per cycle or month and thus the three-monthly injectable to be a long-acting method.(4) Elsewhere, for example in Cambodia, the injectable is considered to be a short-acting method.(5) Unless otherwise stated, in this thesis 'long-acting' contraception encompasses reversible methods (intra-uterine device and implant, but not injectable) and permanent methods.

The World Health Organization (WHO) classifies methods according to *effectiveness*, according to estimated rates of unintended pregnancies per 100 women; either with consistent and correct use, or as commonly used, using data derived from the United States and from developing countries.(6)(7)(8)

In this thesis, contraception is generally described in terms of effectiveness as per the WHO definition with effective modern methods those associated with less than 10% 12-month pregnancy rates as commonly used.(6) Examples of commonly used effective methods include oral contraceptive (OC), injectable, implant, intrauterine devices and permanent methods. Method-specific contraceptive prevalence varies widely across the world.(9) Medical Eligibility Criteria guidance provides information on who can use contraceptive methods safely, including risks of contraceptive use for different medical conditions, often adapted for different settings.(10)

Oral contraception

Oral contraception, often referred to as the 'pill' was first developed during the 1950s, with approvals and increased use in the 1960s.(11) The combined oral contraceptive pill (COCP) generally contains oestrogen and progestogen hormones whereas the progesterone only pill (POP), or 'mini' pill contains one hormone.(6) Combined oral

contraceptives act primarily to prevent ovulation, whereas the POP primarily works by thickening cervical mucus and suppressing ovulation to a variable degree. Worldwide, approximately 9% of married on in-union women used oral contraception in 2015.(9) In the United Kingdom (UK), the COCP and POP accounted for 16% and 6% of use respectively in 2008-9.(12)

The combined pill is taken for three weeks followed by a pill-free week, thus mimicking the menstrual cycle whereas the POP is taken continuously.(6) Advantages of the COCP include regular, lighter and less painful periods and reduced risk of ovarian and uterine cancer. Risks of COCP include a small increased risk of vascular events such as stroke and venous thromboembolism, as well as a small increased risk of cervical and a possible small increase in risk of breast cancer.(6) In contrast, the POP, and progesterone-only contraception in general, have fewer health risks and contraindications to use, but are often associated with menstrual irregularities such as amenorrhoea or irregular bleeding.(6) Both the COCP and the POP pill have a 0.3% 12-month pregnancy rate with consistent and correct use compared to 7-8% as commonly used.(6)

Injectable contraceptive

Worldwide, approximately 5% of married on in-union women used the injectable in 2015.(9) The most commonly used injectable is the progesterone-only injectable 'Depo-Provera' containing depot medroxyprogesterone acetate (DMPA) which was licensed for long-term use in the 1980s.(13) Depo-Provera is administered three-monthly and usually requires administration by a healthcare professional but self-injectable products are available in some countries.(9) The progesterone-only injectable works by thickening cervical mucus, suppressing endometrial growth and

preventing ovulation, and is considered a very effective method with a 0.3% 12-month pregnancy rate with consistent and correct use reducing to 2-3% as commonly used.(6) Advantages of the injectable are that it can be used discreetly and doesn't require remembering to take a pill everyday but users need to remember to attend subsequent appointments. It has few health risks although studies have suggested an increased risk of Human Immunodeficiency Virus (HIV) acquisition amongst women using DMPA.(14) There is conflicting evidence that DMPA reduces bone density and therefore alternative methods are often preferred in women aged <18 years or with risk factors for osteoporosis.(15) The injectable usually causes amenorrhoea over time and menstruation and return to normal fertility can take several months to return to normal after discontinuing.(6)

Contraceptive implants

Contraceptive implants are small flexible tubes inserted under the skin that release a small amount of progestogen over several years (typically 3-5 years depending on product).(6) As with other long-acting methods, the implant is effective and associated with a 0.5% 12-month pregnancy rate with consistent and correct use and as commonly used and users don't have to remember to take pills or attend frequent appointments during its duration of use.(6) As with other progesterone-only methods, the implant has few health risks. The main disadvantages of the implant are that it has to be inserted and removed by trained professionals, and menstrual bleeding changes are commonly experienced.(6) Worldwide, approximately 0.7% of married or in-union women used the implant in 2015.(9)

Intra-uterine contraception

There are two types of intrauterine contraception, the intrauterine device (IUD) and

the Intrauterine system (IUS).(6) Intrauterine contraceptives were the second most common method worldwide in 2015, with 14% of married on in-union women relying on this method.(9) Both have advantages of being effective, forgettable, long-acting methods associated with low discontinuation,(16) but need to be inserted by trained healthcare professionals.

The IUD is a non-hormonal method generally containing copper which is toxic to sperm and prevents fertilization and implantation. The IUD is a cost-effective method given its low cost and long duration of action (5-10 years).(11) Disadvantages of the copper coil can include heavier periods leading to anaemia, and small risks of expulsion, perforation and infection. The IUS is a hormonal method, first introduced in Europe in 1990.(9) It releases a small amount of progestogen and is typically effective for 3-5 years. In contrast to the IUD, the IUS typically results in lighter periods and helps protect against anaemia.(6) However, to date, the cost of the IUS has limited widespread use in resource-poor settings.(17)

Permanent contraception

Permanent methods include male or female sterilisation.(6) Female sterilisation was the most common method globally in 2015. Worldwide, approximately 19% of married on in-union women relied on female sterilisation.(9) Female sterilisation involves fallopian tube occlusion either by applying clips, cutting or cauterising and is a very effective method with a lifetime failure rate of around 1 in 200 women.(6) It is associated with several risks related to the surgical procedure such as risk of bleeding, infection or injury to the bowel or bladder.(6) In contrast, male sterilisation (vasectomy), severing the vas deferens, is more effective (lifetime failure rate of 1 in 2000 men), less expensive to perform and associated with fewer complications than

female sterilisation.(6) However, with the exception of a few countries such as the UK and Australia, male sterilisation is much less common compared to female sterilisation.(9)

Condoms

Condoms are barrier methods that also provide protection against sexually transmitted diseases and require both male and female partner's cooperation.(6) Male or female condoms are not generally considered to be effective methods for to protect against pregnancy as they have 12-month failure rates as typically used of around 10 and 21% respectively, but may be a good choice for women who have infrequent sex, or cannot or prefer not to use hormonal methods.(6) Worldwide, approximately 8% of married or in-union women used condoms in 2015.(9)

Unmet need for contraception

Despite the health benefits of contraception and existence of a range of different methods, there is significant unmet need for contraception. Unmet need refers to fecund women of reproductive age who want no more children or want to postpone having a child in the next two years, but are not using a modern contraceptive method.(18) An estimated 222 million women of childbearing age in 2012 had unmet need for contraception.(19) It has been estimated that if unmet need for modern methods of contraception were met amongst women in developing countries, this could prevent an additional 54 million unintended pregnancies, 26 million abortions (of which half would be unsafe), 79,000 maternal deaths and 1.1 million infant deaths.(19)

Abortion

Globally around 25% of pregnancies resulted in induced abortion in 2010-14, equating to an annual abortion rate of 35 per 1000 women aged 15-44.(20) Induced abortion is medically safe if performed by trained professionals in accordance with recommended guidelines.(21) Although the proportion of abortions that are unsafe is not currently known, almost all abortion-related deaths occur in developing countries, representing 8-18% of maternal deaths, and an estimated 22,500 to 44,000 deaths in 2014.(21) Induced abortions can be broadly categorised as medical or surgical. Surgical abortion is performed by vacuum aspiration (typically for pregnancies up to 15 weeks) or dilatation and evacuation (typically for pregnancies after 15 weeks duration).(22) Medical abortion drugs, first approved in China and France in 1988, generally involve a regimen composed of mifepristone and misoprostol for pregnancies up to 9 weeks.(23)(24) Increasing use of medical abortion has made it more difficult to measure abortion incidence in many countries.(20)

A study looking at evidence from 27 countries in 1998 found that women have induced abortions for a variety of reasons; most commonly to postpone or stop childbearing which could be due to socioeconomic concerns such as disruption of employment, relationship problems with a husband or partner or health problems.(25) A qualitative study in the UK from 2004 found that decisions to have an abortion were mostly related to social and economic context in the women's lives rather than moral views and that similar factors influenced decision-making process regardless of the women's age.(26)

Post-abortion family planning (PAFP): rationale and determinants

Women seeking abortion services often have an unmet need for family planning.(27)

Post-abortion family planning (PAFP) can reduce subsequent unplanned pregnancies

and health risks of repeat abortion, particularly in settings where abortion is illegal and/or unsafe,(28) and was identified as a High-Impact Practice in family planning by a technical advisory group in 2012.(29) Contraception and family planning services are considered one of the five essential elements of post-abortion care, the others being community and service provider partnerships, counselling, treatment, and reproductive and other health services.(30) An observational study in Finland published in 2012 found that women who had three or more abortions had increased odds of subsequent preterm birth or low birthweight outcomes in subsequent pregnancies after adjusting for social factors.(31) Women are at risk of pregnancy almost immediately after having an abortion, with studies showing that more than 80% of women ovulate in the first cycle after abortion.(32)(33) The World Health Organization have recommended a minimum spacing interval of six months in order to reduce risks of adverse maternal and perinatal outcomes.(34)(35) As studies have shown that over 50% of women will resume sexual activity within two weeks of having an abortion and up to 50% do not attend subsequent follow up appointments, contraception should be started as soon as possible to reduce the risk of subsequent unintended pregnancy.(27) It is safe to use a wide range of contraception methods in the immediate post-abortion period, with no evidence that use of hormonal methods adversely affect the efficacy of medical abortion, or vice versa.(10)(27) Intra-uterine devices can be inserted at the time of surgical abortion but should be delayed after medical abortion until the abortion is complete.(27) Observational studies have shown that use of long-acting methods (i.e. the intrauterine device, intrauterine system or implants) have been shown to reduce subsequent unintended pregnancies in women who have had an abortion.(27)(36)(37)(38)

Provision of contraception services when women seek abortion services would appear to be a practical and convenient time to initiate contraception methods to reduce the risk of subsequent unintended pregnancies. However studies assessing contraceptive provision have identified several challenges to providing contraception at the time when women seek abortion services.(27)

On the demand side, it is thought that women may be motivated to start a method at this time, however studies addressing the degree to which women want to discuss contraception at the time of seeking abortion services show mixed findings.(27)(39)

One study in the United States of America (USA) found that 69% of abortion patients felt that the abortion setting was an appropriate one for receiving contraceptive information.(40) However, another study in the USA found that 64% of women did not want to discuss contraception on the day of their abortion mostly because they already knew what they wanted for pregnancy prevention.(41) A study in the UK found that the majority of women considered addressing contraception at the time of seeking medical abortion to be acceptable, provided it was done in a non-judgmental way and that health professionals were not too 'pushy' towards making a contraceptive decision. The authors commented that women already have important decisions to make at the time of seeking abortion services and might feel like they have little agency and that the decision to adopt contraception could represent a process over which they feel able to exercise control.(39) Another study in the USA found that women desired an intimate, friend-like relationship with their providers.(42) Other potential barriers to uptake of PAFP from the demand side include cost of additional services and additional time required in the clinic if opting for a long-acting method.(27)

Several supply side factors can influence provision of contraception at the time when women seek abortion services. Less research has been undertaken exploring healthcare professionals' experiences with providing PAFP but a qualitative study in Scotland found that healthcare professionals considered PAFP to be important in relation to preventing subsequent abortions.(39) However, providers may be concerned that women might be too distressed or overloaded with information to discuss contraception at the time of seeking abortion services.(27) It is not always the case that a full range of contraceptive methods are available to women seeking abortion services, and providers may lack the training and time to provide comprehensive contraception counselling.(27) In this regard, provision of information about abortion via an audiovisual digital video disc in the UK resulted in staff having more time to discuss patient concerns and contraception.(43) Additional training and the time required for insertion have been identified as barriers to provision of long-acting contraception, adding pressure to already busy clinic workloads. Thus it can be more time-consuming to insert an implant or IUD compared with handing over a supply of pills or condoms, even though these methods are associated with higher discontinuation and user failure rates.(27)(44)

Contraception use over the extended post-abortion period

Whilst data is often available from abortion service delivery providers on immediate post-abortion contraception uptake, less is known globally on contraception use following an induced abortion over an extended time period. It is not possible to determine patterns of contraceptive use using data from Demographic and Health Surveys as they do not distinguish between induced and spontaneous abortion, and thus are rarely analysed for studying post-abortion contraception trends.(28)

A review of post-abortion contraception in 2015 found four studies examining patterns of contraception use, two in India and two in Nepal.(28) A cross sectional study in India found that only 30% of women used any method following an abortion, induced or spontaneous. Overall, 40% discontinued spacing methods by 24 months.(45) A cross sectional study in Nepal found that women who had an induced abortion were more likely than postpartum women to adopt a contraception method within 12 months (56% vs. 34%; $p<0.001$) but they were more likely to discontinue use within 12 months (48% vs. 44%; $p=0.016$). Discontinuation was more likely with traditional methods compared to modern spacing methods.(46) A cohort study in India found that 94% of women who had a surgical abortion and 89% of women who had a medical abortion were using contraception at six months. There was higher use of female sterilisation at one-month among women having surgical compared to medical abortions (25% vs. 1%). The six-month discontinuation rates at six months were similar; 8% for surgical and 5% for medical abortion.(47) A cohort study in Nepal found that one in three women seeking abortion services received no information on contraceptive method. Women not living with a husband or with no children were less likely to receive counselling. Lack of equipment and trained staff meant that 48% of women selecting LARC and 83% of women selecting female sterilisation left the facility without an effective method.(48)

Overall, these studies show wide variation in patterns of contraceptive use in the post-abortion period and highlight some of the challenges in providing contraception at the time when women seek abortion services. Additional data on PAFP can be obtained from the control arm of trials of interventions to increase contraception use and are discussed in Section 1.3.

Theory on determinants of contraception use

This section introduces theory on the determinants of contraceptive use. Michie et al described theory as *“a set of concepts and/or statements with specification of how phenomena relate to each other”*, and behaviour as *“anything a person does in response to internal or external events”*.(49) Various theories and models have been developed to describe and predict contraceptive use for pregnancy avoidance.(50)(51) These broadly include developmental models which emphasise contraception use as involving a series of stages, and decision-making models which examine the psychological factors that predict contraception use. Developmental models include Lindemann’s Three-Stage theory and Rains’s model. Decision-making models include the Subjective expected Utility Theory, the Health Belief model, the sexual behaviour sequence model and Herold and McNamee’s model.(52)

Lindemann’s Three-Stage theory suggests that individuals are more likely to use contraception as they progress through three stages; the natural stage where intercourse is relatively unplanned and contraception use is unlikely, the peer prescription phase where the individual seeks contraceptive advice from friends and less effective contraception is used, and the expert stage where the individual has incorporated sexuality into their self-concept and will obtain professional advice and plan contraception use.(53)

Rains’s model suggests that contraception use is more likely to occur when individuals believe that sexual activity is ‘right for them’ and involves four stages.(54) The first stage is falling in love, providing a rationale for sex. The second stage is having an exclusive long-term relationship .The third stage is sexual intercourse becoming an acceptable behaviour. The fourth stage where individuals accept themselves as sexual

and planning sex for the future predicts reliable contraception use.

The Subjective Expected Utility Theory is the basis of most decision-making models that regard contraception use resulting from an analysis of different variables.(50)

Subjective utility theory suggests that individuals make decisions based on subjective estimates of potential costs and benefits of a particular behaviour. In the context of contraception use, individuals consider the costs and benefits of pregnancy compared to the costs and benefits of contraception.(55) This theory is predominantly individualistic with a greater emphasis on individual cognitions compared to relationship and social contexts.(50)

The Health Belief model was initially developed in the 1960's in order to predict preventive health behaviours and has been subsequently used to predict a wide variety of health-related behaviours.(56) It is a social cognition model that attempts to place the individual within the context of relationships and broader social norms.(50)

The health belief model has been used to predict contraception use considering variables such as knowledge and attitudes about sex and contraception, previous experiences and relationship status.(57)

The sexual behaviour sequence model is based on the theory of reasoned action and with the addition of sexual arousal and emotional responses to sex. The theory of reasoned action is also a social cognition model that examines the predictors and precursors to health behaviour.(58) This model suggests that decisions about contraception are made in the context of both rational information processing and factors such as how sexually aroused an individual is at the time of making a decision about contraception.

Herold and McNamee's model is made up of six variables; parental and peer group

norms, number of lifetime sexual partners, guilt about intercourse and attitudes to contraception, involvement with current partner, partner's influence to use contraception and frequency of intercourse.(59) This model is different from other models of contraception use as it includes details of the relationship.(50)

Developmental models describe contraception use resulting from the transition through a series of changes do not examine the psychological factors that may speed up or delay transition through the series of stages. Decision-making models, in contrast, emphasize individuals' cognitions within the context of relations and social norms, to varying degrees.(50)

Sheeran et al proposed combining developmental and decision-making perspectives.(52) Sheeran's model combines developmental and decision-making approaches to contraceptive use and it the principal model referred to in this thesis as it includes a combination of individual and social variables. Reviewing nine theoretical accounts of contraceptive behaviour, Sheeran proposed that contraceptive use is a product of background, intrapersonal, interpersonal and situational factors.(52)

Background (demographic) factors that have been found to influence contraception use include age, sex, ethnicity, social class and education.(60)(61) Intrapersonal factors include knowledge, attitudes and personality. Studies have shown mixed findings between associations between knowledge about contraception, fertility and behaviour.(62)(50)(57) Several studies have found associations between positive attitudes towards contraception and actual use.(63)(64) Studies have shown that different personality types can be associated with contraception use. Conservatism was shown to be negatively associated with contraception use.(65) An internal locus of control, sex guilt and sex anxiety have been found to be positively associated with

contraception use.(59)(66) Interpersonal factors include the role of partners, parents and peers. Aspect of partner relationships that may influence contraception use include duration of relationship, intimacy, type of relationship, exclusivity and ability to discuss contraception.(67)(68) There is some evidence that mother and daughter communication and parental permissiveness are related to contraception use.(59) Similarly, contraception use can be associated with peer permissiveness and peer's own contraceptive behaviour.(69) Situational factors identified that contribute to contraceptive use include spontaneity of sex, substance use prior to sex, accessibility of contraception. Spontaneity of sex can be a reason for not using contraception.(70) Use of alcohol or drugs may be associated with risky sex.(71) Easy access to contraception in general and at the time of contemplating sex has been shown to be positively associated with contraception use.(72) I will next review literature on contraceptive trends and determinants in Cambodia considering these background (demographic), intrapersonal, interpersonal and situational variables.

1.2 Contraceptive trends and determinants in Cambodia

Cambodia experienced a baby boom following the end of the Khmer Rouge-led genocide of 1975-1979.(73) However, Cambodia is now in the process of a demographic transition from high birth and death rates to lower birth and death rates and has a young population with 43% aged less than 20 years.(74) The total fertility rate (TFR) decreased considerably over the last three decades from 6 in 1980, to 3.4 in 2005, 3.0 in 2010 and 2.7 in 2014. At the same time, the maternal mortality rate (deaths per 100,000 live births) decreased from 472 in 2005 to 206 in 2010, and to 170 in 2014.(74)(75)(76)(77)

Family planning services with modern contraceptives became available in 1991 in Cambodia, supported by international non-governmental organisations. In 1994 the Cambodian government started to implement its own family planning programme which included introduction of services at health centres. The Maternal and Child Health Plan 1994-1996 and Birth Spacing Policy for Cambodia in 1995 introduced specific objectives for lengthening birth intervals.(73)

Reflecting Cambodia's pluralistic health system, contraception is available in Cambodia through a range of service delivery systems including public health facilities (e.g. hospitals/health centres), private health facilities (e.g. private clinics/pharmacies and non-governmental organisations) and community distribution. The 2014 Cambodia DHS survey reported that users of modern contraceptives obtain their methods from the public sector more than the private sector (47% vs. 39%) and less so from other sources such as community distribution (8%) but this varied by method. Women were more likely to obtain female sterilisation (76% vs. 22%), IUD (53% vs. 35%) and injectables (65% vs. 48%) from the public sector vs. the private sector, but less likely to obtain oral contraceptive (35% vs. 42%) and male condom (17% vs. 65%), with similar proportions for implant (49% vs. 48%).(74) Almost all oral contraceptive (95%) and condom (88%) users were using a socially marketed contraceptive brand.(74)

The Cambodia DHS reported that knowledge of any contraceptive method and any modern method was nearly universal. Overall, 56% of married women were using any contraception method in 2014, but there was substantial variation by province ranging from 63% in Phnom Penh to 42% in more rural provinces. Contraception use was reported to be higher amongst urban women, women of higher parity, and women with increasing education and wealth.(74)

The cost of obtaining contraception varies according to where it is obtained and incurs a user charge in most cases.(78) Typical fees for one month of the oral contraceptive or a three-monthly injection from a local healthcare worker operating from the market or their house in 2012 were reported to be \$0.25 USD¹ and \$0.5-1 respectively.(79) Long-acting methods such as IUD and implant are typically less available in rural areas and therefore are likely to incur additional opportunity costs related to lost income and travel to a bigger clinic.(79) Typical user fees for contraception at private/non-governmental clinics in 2013 were as follows: IUD insertion (\$5), implant insertion (\$25), three-monthly injectable (\$1), one cycle of oral contraceptive (\$0.40) but fee's can be waived on a case-by-case basis for clients who are unable to pay².

In 1997 in response to the high maternal mortality, estimated at 900/100,000 live births, the abortion law was reformed to allow abortion on request up till the 12th week of pregnancy. However, after the abortion law reform, implementation of safe abortion services was slow and it was only following the introduction of the national Comprehensive Abortion Care (CAC) training curriculum in 2007 that safe abortion services were introduced in public hospitals in Phnom Penh city and the provinces, non-governmental organisation clinics, and some registered private clinics and registered pharmacies.(73)(75) The medical abortion pack 'Medabon' containing mifepristone and misoprostol was approved by the Cambodia Ministry of Health in 2010.(75)

The 2005, 2010 and 2014 Cambodia demographic and health surveys reported the 'proportion of women reporting having had an abortion in the previous 5 years' rather than the standard indicator of abortions per 1,000 women. The proportion of women

¹ All costs in this section are in United States Dollars

² Source: internal Marie Stopes International Cambodia data

reporting having had an induced abortion in the previous five years increased from 4 in 2005 to 5 in 2010, to 7 in 2014.(74)(76)(77) The proportion of women reporting an abortion in their lifetime increased from 8% in 2005 to 12% in 2014. (74)(76) The proportion of women having a medical abortion rather than a surgical abortion increased from 31% in 2010 to 47% in 2014.(74)(77) The abortion rate was estimated to be 50 per 1,000 women aged 15-44 using data extrapolated from a survey conducted in 2005.(80) This abortion rate was estimated in a subsequent paper using demographic and health survey and national prospective data to be 21 per 1000 women in 2005 increasing to 28 per 1,000 women aged 15-44 in 2010.(81)

The 2014 Cambodia DHS survey reported that the practice of abortion occurs throughout Cambodia but with variation by residence and province. The proportion of women reporting one or more abortions in their lifetime was 17% amongst urban women compared to 11% amongst women in rural areas; 19% of women in Phnom Penh reported ever having an abortion compared to 3% in the rural Modul Kiri and Ratanak Kiri provinces. Women were more likely to report having had an abortion if they were ever married, or had less education.(74)

The same survey reported that 44% of abortions took place at a private health facility, compared to 32% at the respondent's home, 16% in a public health facility and 8% at other home. The proportion of women using a health facility was slightly increased amongst urban women, but there were no marked differences by education. Younger women aged 15-34 were less likely to use a public health facility compared to older women (13% vs. 19%), more likely to have an abortion at their home (35% vs. 26%) with no apparent difference in use of private health facilities (45% vs. 43%).(74)

Despite availability of safe abortion, some women continue to seek abortion from

unskilled providers, herbalists, drug sellers, pharmacists and traditional medical practitioners or induce their own abortions.(82)(75) This could be due to lack of awareness of the legality of abortion and other identified barriers such as shortages of trained healthcare workers, infrastructural barriers, provider conscientious objection or expensive fees.(82)(81)

Fees reported to be charged for abortions reported in a study conducted by Options in 2008 ranged from under \$10 for an abortifacient pill to \$20-40 for a surgical abortion in the first trimester, to over \$100 for an abortion at the “big hospital” in the second trimester. The study authors commented that the price of abortion should not be seen as a simple barrier to access but a determinant of provider and method choice.(73)

Petit et al reported that the recommended retail price of the medical abortion product ‘Medabon’ in 2012 was \$4.5 but observed to be sold for \$10-15 per pack in pharmacies.(75) A study conducted by Marie Stopes International Cambodia in 2009 of women seeking abortion services found that women reported spending between \$1.25 and \$15 for medical abortions and between \$10 and \$100 for surgical abortions with prices in urban areas being significantly higher.(83) Typical user fees for abortion as part of a comprehensive abortion service package including consultation, post-abortion care and post-abortion family planning at private/non-governmental clinics in 2013 were \$20 for medical abortion and \$25 for surgical abortion³. In contrast, fees for traditional abortion medicine were reported in Petit et al’s 2011 study to be around \$3.(78) In addition to service user fees, women have to incur travel and opportunity costs. A study by Potdar et al in 2008 found that women reported losing up to 36 days of their own productive time and giving up as much as \$100 of their household income

³ Source: internal Marie Stopes International Cambodia data

to receive appropriate abortion care, in a country with a gross domestic product per capita of \$306 at the time.(84)

The 2008 Options study sought to learn about perceptions, attitudes and behaviours relating to abortion and contraception in Cambodia and found that women chose to have abortions for numerous reasons including ill health, pre-marital pregnancy, to widen birth interval, competing family responsibilities and poverty.(73)

The 2010 Cambodia Demographic and Health Survey (DHS) reported that 81% of women of reproductive age wanted to delay their next child by at least two years, or have no more children, with only 35% using a modern contraceptive method.(77) In 2014, 77% of women reported wanting to delay a pregnancy by at least two years with a slight increase of 39% using a modern contraceptive method.(74) Table 1 shows estimates of contraception use in 2015 for commonly used methods worldwide and in Cambodia. The 2014 Cambodia DHS reported that the most widely used method was the daily pill (18%), followed by withdrawal (15%) and injectables (9%).(74)

Table 1: Estimates of contraceptive prevalence by method among married or in-union women aged 15-49, 2015

	Any method	Female sterilisation	Male sterilisation	OC	Injectable	IUD	Implant	Condom
World	64%	19%	2.4%	9%	5%	14%	0.7%	8%
Cambodia	58%	3.1%	0.1%	19%	10%	5%	2%	2%

Source: Trends in Global contraceptive use worldwide, 2015. United Nations, Department of Economic and Social Affairs(9)

The observed rise in induced abortion and contraception use in Cambodia is typical of settings where fertility levels are falling,(85) and suggests unmet need for contraception. Reducing unmet need could result in improved health indicators in Cambodia, where despite improvements, maternal and child mortality remains high.

Determinants of contraceptive use in Cambodia

Considering Sheeran's model, analyses of DHS survey data on contraception use in developing countries have identified *background* factors associated with contraceptive use.(86)(3)(16) The Cambodia DHS reported increased contraceptive use with increasing parity, wealth, and levels of educational attainment.(77) Whilst few data exist on post-abortion contraception use from DHS surveys, a cross-sectional study in Cambodia examined determinants of contraceptive acceptance amongst women seeking abortion services. Factors associated with contraceptive acceptance included increased parity and range of available contraceptive methods where abortion services are provided.(82)

An analysis of 52 developing countries with surveys since 2001, including Cambodia, examined reasons for non-use of contraception amongst married women with unmet need for contraception.(3) These reasons can be organised according to the factors proposed by Sheeran as follows: *intrapersonal* e.g. lack of *knowledge* about methods or source of methods or concern about *health* or side-effects, *interpersonal* e.g. husband/partner opposed to use, and *situational* e.g. reduced *exposure* to sex (for example if husband or partner works away), *fertility related* (menopausal, subfecund, postpartum amenorrhoeic or breastfeeding) or *other* (access, cost, convenience).

Table 2: Reasons for non-use of contraception by currently married women

	Exposure	Fertility related	Opposed	Knowledge	Health concerns	Other	Total
Cambodia 2010 DHS	23	10	12	1	48	6	100
Total (based on 15 DHS surveys conducted in Asia, North Africa & Europe)	28	17	19	1	29	6	100

Adapted from Table 11: Reasons offered for non-use of contraception by currently married women in need of a modern method in Westoff C. Unmet Need for Modern Contraceptive Methods: DHS Analytical Studies No. 28. Calverton, Maryland, USA: ICF International; 2012.(3)

The findings in Table 2 are consistent with the discontinuation literature which

identifies health concerns, including side-effects as the most common reasons for discontinuation, occurring most often during the first few months of use.(16)(87) However, health concerns are particularly prominent in Cambodia, accounting for almost 50% of non-use. The findings are supported by research conducted in Cambodia. A cross-sectional study reported side-effects as the most important reasons for not trying or discontinuing contraception.(88) A focus group study of poor married women of reproductive age found that women reported a high level of side-effects from contraception. Furthermore, women reported switching from modern methods to less effective methods, either to take a break or discontinue modern methods altogether.(89) The Options study also reported that widespread rumours and fears about contraceptive side-effects presented a major barrier to uptake, continuation and consistent use. The authors suggested that Cambodia was still in an “early adoption” stage with regards to perceptions of family planning and behaviour around contraceptives characterised by low levels of knowledge, inaccessible and poor quality services, numerous and often inconsistent stories and rumours about side-effects, incorrect use of contraceptives, lack of choice, and sub-optimal provision by providers.(73)

Experience of negative side-effects may be related to traditional health beliefs in Cambodia. An anthropological study explored practices and representation related to reproductive health and contraceptive methods in Cambodia.(78) Petitet reported that in Cambodia, abundant menstruation (the expulsion of ‘bad blood’) is viewed as a sign of good health and fertility. Contraceptive methods that result in reduced menstruation (for example the injectable) can cause women to worry where the blood is retained, and discontinue the method to wait for a menstrual period. Many women

reported never using or discontinuing contraception because they feared or experienced side-effects. One woman who had five previous abortions reported:

“With the contraceptive pill we always have problems, bellyaches for two months or more, headaches. Abortion only takes 10 minutes and then that’s over.”

Although reported less than health reasons, factors related to knowledge, access, cost and autonomy are important reasons for non-use of contraception in Cambodia.

Women often obtain information about contraception from friends and relatives, with myths and rumors commonplace.(79)(90) Furthermore, not all women have full autonomy over health care decision making. The Cambodia DHS reported that whilst 45% of married women make decisions about their own healthcare by themselves, 45% make decisions jointly with their husbands, and in 9% the husband decides.(77) Sex workers in Cambodia likely have even less autonomy, with a cross-sectional study reporting that about half of women interviewed stated having been coerced by clients into unprotected sex.(91)

Finally, access and cost can influence choice of contraceptive method, particularly for poor women living in rural areas. Women have to consider the cost of transportation and opportunity cost of not working to travel to provincial towns to obtain long-acting methods, which are often not available at local health centres.(79)

1.3 Interventions to improve uptake and adherence to contraception

Despite the significant literature on determinants of contraception use and evidence that use of long-acting reversible contraception can reduced subsequent unintended pregnancies, systematic reviews have found limited evidence for interventions to improve use of contraception and PAFP.(92)(93)(94)

A systematic review of randomised controlled trials of effectiveness of contraceptive

counselling following an abortion by Ferreira et al in 2009 identified three studies.(94) A study in the UK in 2004 assessing specialist contraceptive advice and enhanced provision found no significant difference in contraceptive use at four months or abortion rate after two years. However, women in the intervention group were more likely to be using contraceptive implants at four months (32% vs. 6%; $p<0.001$). (95) A study in Iceland in 2003 assessing counselling provided by a specially trained family planning nurse found no significant difference in contraceptive use between the two groups.(96) A study in Italy in 2007 assessing a patient-centred counselling intervention found increased knowledge and attitudes regarding contraceptive methods and increased use of effective contraception at one and three months.(97) A meta-analysis of the three trials found no difference between intervention and control groups with the authors concluding that there was no evidence indicating that contraceptive counselling is effective in increasing contraceptive use after an abortion.(94)

A systematic review of post-abortion family planning counselling and services for women in low-income countries by Tripney et al in 2013 identified 15 studies.(93) It was not possible to do a meta-analysis due to differences in interventions and outcomes. Seven of the studies that used a comparative design (pre-post studies with or without a control group) reported increased use of modern contraceptive use compared with the non-program group. One study assessed repeat pregnancy and abortion, a matched controlled study in Zimbabwe, and reported that women receiving counselling and free contraception prior to hospital discharge had fewer unintended pregnancies (15% vs. 34%; $p<0.001$) and repeat abortions (2.5% vs. 5.3%; $p=0.23$) at 12 months compared with standard care.(98) However, given the paucity of

high quality evidence, the review authors concluded that the evidence for post-abortion family planning counselling in low-income countries to address the problem of unsafe abortion was inconclusive.(93)

Whilst the limited evidence for interventions to increase contraception use may be partly due to a limited number of high quality, adequately powered trials, the focus of the interventions need to be examined. Interventions have often focused on adherence to a specific method, often OC, which may be less effective than interventions that anticipate method-specific discontinuation and facilitate safe method switching.(16) Furthermore, there have been calls for increased attention to theory of behaviour change in designing and evaluating interventions for contraception use.(99) It is important to distinguish between theories of *behaviour* and theories of *behaviour change*. Whilst Sheeran's framework is helpful in understanding factors that influence contraception use (i.e. existing behaviour), 'behaviour change interventions' can be considered 'coordinated sets of activities designed to change specified behaviour'.(100)

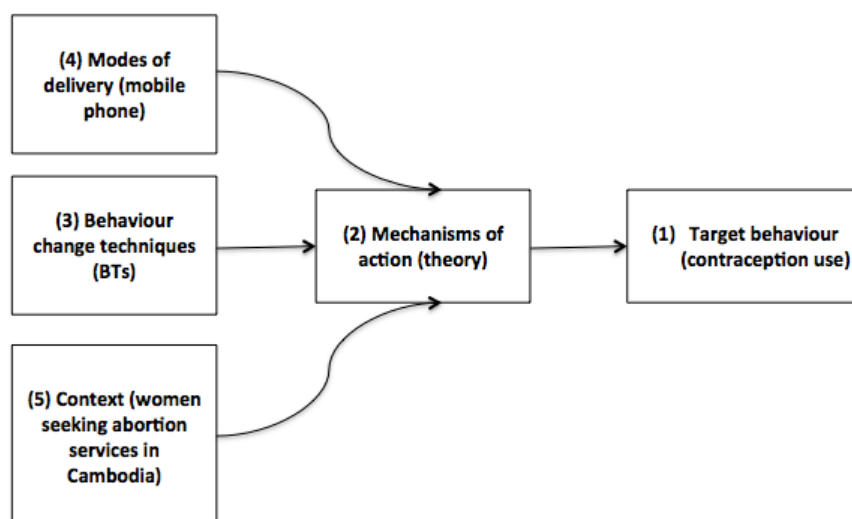
Many theories or models of change are used in the health behaviour field.(101) A systematic review in 2012 identified 83 behaviour change theories developed to guide design, implementation or evaluation of interventions.(102)(49) Four theories accounted for 63% of articles found; the Transtheoretical Model of Change, Theory of Planned Behaviour, Social Cognitive Theory, and the Information-Motivation-Behavioural-Skills Model.

In the field of contraception, a Cochrane review of trials that tested a theory-based intervention for improving contraception use identified 17 trials, most of which focused on adolescents in the USA.(101) Half of the trials addressing contraception use

showed some effect and used several different theories including motivational interviewing, social cognitive theory, other social cognition models and the Health Belief model.

Given this plethora of theories, intervention designers who acknowledge that drawing on theory can be useful are faced with a question as defined by Michie et al: *“for target behaviour X for population Y, in context Z with constraints W on intervention delivery, which theory is likely to be most appropriate and informative?”*,(49) and sought to address this by developing a simple Behaviour Change Ontology linking five elements: 1) behaviours, 2) theories and constructs, 3) behaviour change techniques (BCT), 4) modes of delivery and 5) contexts (setting and population).(103) In the context of this thesis, in Figure 1, the target behaviour (box 1) represents contraception use, the mode of delivery (box 4) is mobile phone and the context (box 5) is women seeking abortion services in Cambodia.

Figure 1: Scheme for a simple behaviour ontology



Source: Adapted from 'ABC of behaviour change theories', p473 (Michie et al, 2014)(49)

Michie et al conducted a systematic literature review and evaluation of existing frameworks when developing the 'Behaviour Change Wheel'.(100) Unlike other

theories focusing on current behaviour, it seeks to specify how to bring about change in behaviour. A review of existing behaviour change frameworks led to the development of the behaviour change framework that considers broader individual, group and environmental perspectives that influence behaviour change.(100) At its core is the COM-B model (Capability, Opportunity, Motivation – Behaviour) ‘behaviour system’ involving three essential conditions; *capability* (an individuals psychological and physical capacity to engage in the activity concerned), *motivation* (the brain processes that energize and direct behaviour which include conscious decision-making and emotional responding) and *opportunity* (factors that lie outside the individual that make behaviour possible).(100)

Interventions can be characterized in terms of their effective components, or ‘techniques’. Abraham and Michie presented a taxonomy of behaviour change techniques used in interventions in 2008, identifying 26 BCTs, for example provision of information on risks, consequences of actions, or conversely, encouragement and goal setting.(104) In 2013, Michie et al presented a more exhaustive taxonomy of 93 distinct BCTs clustered into 16 groups agreed by international consensus.(105)

We considered both the determinants of contraceptive use and theory of behaviour change when developing the conceptual framework for our mobile phone-based intervention which is presented in Chapter 3, and coded the intervention according to Abraham and Michie’s taxonomy of BCTs in Chapters 2 and 7.

1.4 Overview of interventions delivered by mobile phone ‘mHealth’

The field of ‘mHealth’

Since the first commercially available handheld mobile phone was officially unveiled in 1983,(106) worldwide mobile phone subscriptions grew to 92 per 100 people in low-

and middle-income countries and 122 per 100 people in high-income countries in 2016.(107) Mobile phones have evolved from devices to make phone calls and text messages in the 1990's,(108) to smartphone's, enabling interactivity and exchange of information, text, data and images in the 21st century.(109)

The term 'mHealth' was first thought to have been coined by Robert Istepanaian and defined in 2005 as the use of '*emerging mobile communications and network technologies for healthcare*'.(110) mHealth was subsequently defined at the inaugural mHealth summit in 2009 as '*the delivery of healthcare services via mobile communication devices*',(111) in 2010 as the '*use of mobile technologies for health*',(112) and in 2011 by the WHO as '*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*'.(113)

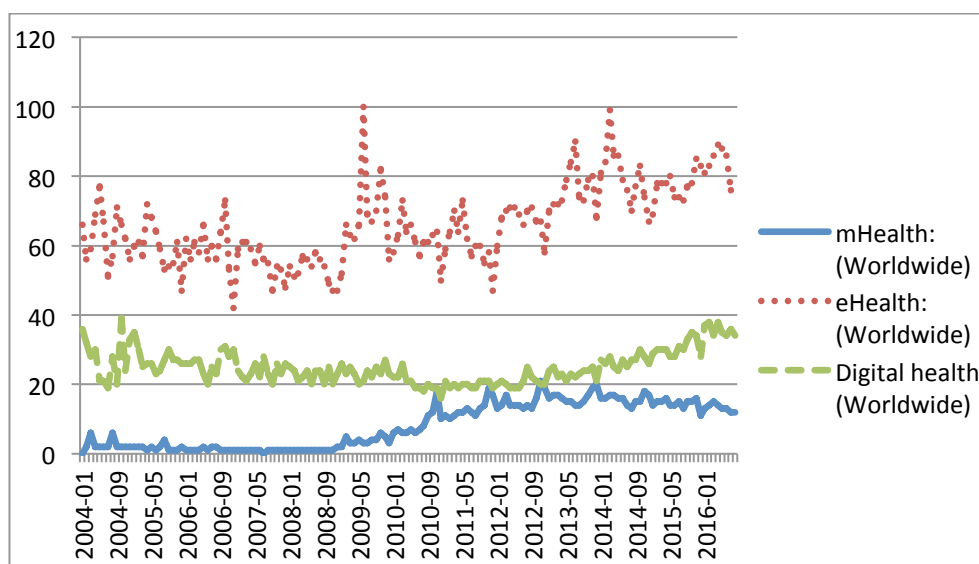
What differentiates 'mHealth' from interventions delivered by landline phones or call-centres is the 'mobile' aspect. Interventions delivered by mobile phone have advantages over face-to-face or healthcare delivery by landline phone as support can be delivered inexpensively wherever the person is located, when it is needed.(114) In particular, interventions delivered by mobile phone have the potential to reach out to youth and rural populations, where geographical distances can restrict access to services. Behaviour change techniques used in face-to-face interventions can be modified for mobile phones.(115) Interventions delivered by mobile phone can utilise different functions of mobile phones and involve different modes of communication for example, text message, voice messages, and smartphone applications and may involve one direction or two-way (interactive) communication.(116)

A number of journals, organisations and networks have been created within the

discipline of mHealth. mHealth organisations and networks include the 'mHealth working group' (created in 2009') and 'mHealth knowledge'.(117) mHealth initiatives have been documented in the 'mHealth compendium' and on websites such as mHealthevidence.org.(118)(119) Academic journals include The Journal of mHealth (<http://www.thejournalofmhealth.com>; first issue Feb 2014) and Journal of Mobile Technology in Medicine (<http://www.journalmtm.com>; first issue March 2012).

Figure 2 shows that Google searches for 'mHealth' increased significantly in the years following 2008. However, it would appear that in recent years the term 'Digital health' is gaining more popularity if compared to 'mHealth'. An example of this would be the change in name of the 'mHealth working group' to the 'Global Digital Health Network' to encompass mHealth, eHealth and information and communications technology (ICT).(120)

Figure 2: 'mHealth', 'eHealth', 'Digital health' Google searches: interest over time (2004-16)



Data source: Google Trends (www.google.com/trends). Numbers represent search interest relative to the highest point on the chart. A value of 100 represents the peak popularity for the term, a value of 50 means that the term is half as popular. A score of 0 means the term was less than 1% as popular as the peak.

This shift in terminology from 'mHealth' to 'Digital health' may reflect confusion about what is and is not 'mHealth', reflecting increasing use of internet on smartphones and tablets moving away from the traditional focus on text and voice messages and phone

calls. For the purpose of this thesis I refer to mHealth as *'interventions delivered by mobile phone to improve health'*, but continue to use term 'mHealth' when describing use in contexts where the term 'mHealth' is commonly used, for example by service providers.

To date, interventions delivered by mobile phone have been designed to improve health service delivery, client health outcomes and as tools for health research. Interventions can be designed for health researchers, healthcare professionals, patients, or the general population, as per Free et al's conceptual framework for mobile electronic device intervention classification (Figure 3).(114) Interventions for patients include those that aim to improve chronic disease management, medication adherence, appointment attendance, or change health behaviour.(115)(121) Labrique et al categorised 12 common application domains for mHealth as per Figure 4. The domains most relevant to this PhD are those focusing on improving health outcomes related to contraception use; thus interventions for patients and the general population for medication adherence, appointment attendance, and behaviour change (Figure 3) and client education and behaviour change (Figure 4).

Figure 3: Conceptual framework for mobile electronic device intervention classification

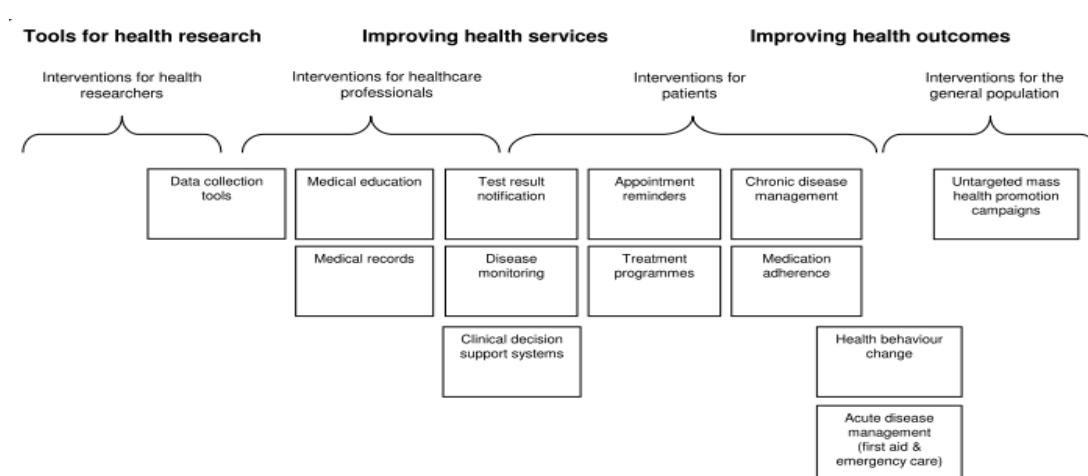


Figure 1 Conceptual framework for mobile electronic device intervention classification.

Source: The effectiveness of M-health technologies for improving health and health services: a systematic review protocol (Free et al, 2010)

Figure 4: Twelve Common mHealth and ICT Applications



Source: mHealth innovations as health system strengthening tools: 12 common applications and a visual framework (Labrique et al, 2013)

Evidence for interventions delivered by mobile phone

A number of systematic reviews in recent years have assessed the evidence for interventions delivered by mobile phone, either looking at a range of health outcomes,⁽¹¹⁵⁾⁽¹²²⁾ or specific healthcare fields such as smoking cessation or anti-retroviral therapy (ART) adherence.⁽¹²³⁾⁽¹²⁴⁾ Some key reviews are outlined as follows.

A systematic review of controlled trials of interventions delivered by mobile phone by Free et al in 2013 identified 75 trials. Four trials had low risk of bias. Simple text message medication reminders had at best small effects (Risk Ratio (RR) 1.00, 0.77–1.30), whilst two multi-faceted interventions were shown to improve health outcomes.⁽¹¹⁵⁾ The txt2stop intervention, comprising personalised text messages was associated with increased objectively verified smoking cessation in the UK (10.7% vs. 4.9%; RR 2.20, 1.80–2.68; $p < 0.0001$) and was shown to be cost-effective.⁽¹²⁵⁾⁽¹²⁶⁾ The WelTel (Lester) trial in Kenya evaluated a multi-faceted intervention for ART medication adherence.⁽¹²⁷⁾ Participants were sent weekly text messages in the local

language asking “*How are you?*” and were instructed to respond within 48-hours if they were doing well or if they had a problem. Health workers would then phone those who said they had a problem or who failed to respond. Medication adherence was higher in the intervention group (RR for non-adherence 0.81, 0.69-0.94). The intervention for the MOTIF trial used a similar approach to Lester and is discussed further in Chapter 3. Free et al’s systematic review found that interventions for other conditions showed suggestive benefits in some cases but the results were not consistent.(115)

A systematic review by Hall et al in 2013 assessed evidence on the impacts of mobile technologies on health outcomes in low- and middle-income countries, not limited to high-quality trial evidence. The review identified 76 papers, 20 of which were in the domain of client education and behaviour change in areas such as tuberculosis and diabetes management.(122) One paper on increasing knowledge and changing behaviour around contraception was identified, a pilot study to evaluate the acceptability, information, access and potential behavioural impact of the Mobile for Reproductive Health (m4RH) text message programme in Kenya.(128) The m4RH programme was subsequently assessed with a randomised controlled trial discussed in Section 2.8.

A systematic review by Wald et al in 2015 comparing one-way versus two-way text messaging on improving medication adherence found that interactive two-way text messaging was associated with improved medication adherence compared with one-way text messaging.(129) Three studies of two-way messaging were identified, but all of the interventions also involved telephone counselling. One of these studies was the WelTel trial described above. A trial by Maduka and Tobin-West also evaluated an

intervention to improve HIV medication adherence in Nigeria.(130) The intervention comprised bi-weekly medication reminder text messages that encouraged participants to acknowledge receipt of the message and indicate if they required further information or counselling. In this case researchers would provide counselling support as required by telephone. The intervention also comprised four adherence counselling sessions lasting between 45 and 60 minutes. Medication adherence was higher in the intervention group (77% vs. 56%; RR 0.75, 0.55-0.96; p=0.022).

The third study identified in this review assessed an intervention by Wald et al to improve adherence to cardiovascular treatment in the UK.(131) The intervention comprised text messages over a six-month period asking participants to reply indicating whether they had taken their medication. Patients who had not taken their medication or not responded were telephoned to determine reasons for not taking medication and discussing with view to resolving the issue. The authors reported a 16% absolute improvement in non-adherence (participants taking less than 80% of prescribed regimen) in the intervention group (9% vs. 25%; p<0.001).

A systematic review of mobile text messaging for promoting adherence to antiretroviral therapy conducted by Horvath et al in 2012 identified two RCTs from Kenya, one of which was the Lester trial.(132) The other trial by Pop-Eleches et al compared different intervals and lengths of text messaging with standard care.(132) Adherence of greater than 90% was higher in amongst participants receiving weekly text messages compared with the control group (53% vs. 40%; p=0.03). The systematic review authors concluded that there is high-quality evidence that mobile phone text messaging at weekly intervals is efficacious in enhancing adherence to ART.(123) Subsequent to this review was a trial to improve adherence to HIV treatment in 2014

in India by Shet et al.(133) The intervention was described as being interactive in that it comprised weekly voice messages that asked participants to respond if they were taking their medications as prescribed. However, the intervention did not involve phoning participants who reported not taking their medication. The intervention was not associated with a significant difference in time to virological failure.

Some observations can be made from the systematic reviews and studies described in this section. The area of interventions delivered by mobile phone (mHealth) is a dynamic one with a growing evidence base and it is challenging to keep up-to-date with the research across all healthcare fields, study designs and mHealth domains. The trials of ART adherence are encouraging in that they demonstrate that interventions delivered by mobile phone can be delivered to a group in which confidentiality and privacy are important. In general it can be observed that multifaceted, more intensive, interventions delivered by mobile phone appear to be more effective than more simple uni-faceted interventions such as one-way medication reminders.(115)(123)(124) This is consistent with adherence research demonstrating that multifaceted, more intensive, interventions can be effective but uni-faceted interventions have modest benefits.(134)

Another observation concerns the description of the interventions. The 'two-way messaging' interventions in Wald's review all involved contacting patients by phone for additional support depending on the response to the text message and the Lester intervention was also described by the authors and in the Horvath review as a text message intervention even though this also involved contacting patients by phone for additional support.(129)(127)(123) The finding that two-way interactive messaging

interventions appear to be more effective than one-way interventions may be because several of these interventions have involved phone counselling.

Most reviews and trials focused on health outcomes. Whilst evidence for interventions delivered by mobile phone on health outcomes is increasing, few studies reported on their cost-effectiveness which may be a contributing factor to why the majority of interventions delivered by mobile phone have not been scaled up.(135)(136)(122)

1.5 mHealth in Cambodia

In 2012, in Cambodia, there were an estimated 19 million mobile subscriptions covering a population of 14 million.(137) Cambodians do appear to be enthusiastic mobile phone users, as can be witnessed during daily life in urban and rural areas. In 2012 there was significant interest in mHealth in Cambodia, as observed by a number of organisations such as InSTEDD South East Asia and the Open Institute developing and implementing initiatives utilising mobile phones.(138)(139)(140) However, a number of operational challenges facing mHealth programmes in Cambodia have been identified.(141) Cambodian mobile phone users often have multiple Subscriber Identification Module (SIM) cards and share phones which can make it difficult to maintain contact with users. Cambodians often prefer to use their mobile phone for voice calls rather than text messages for two reasons. First, whilst literacy levels are 90% in urban areas, this figure is lower (69%) in rural areas.(77) Second, lack of Khmer (Cambodian) language capability on many phones means that even if users can read the Khmer script, they can only text using Roman letters. Despite these challenges, appropriately designed mHealth interventions have potential to reach out to the 80% of Cambodians living rural areas, with the least access to health care.(77)

1.6 Literature review of interventions delivered by mobile phone for contraception

As of 2014, no systematic reviews had examined interventions delivered by mobile phone to increase contraception use. I conducted a literature review during February 2014 for my PhD upgrading report to identify randomised controlled trials of interventions delivered by mobile phone for improving uptake and adherence of contraception and additional relevant literature on interventions delivered by mobile phone and contraception.

Three trials were identified that fulfilled the inclusion criteria comparing a mobile phone text message intervention compared to standard care (Castano, Hou and Tsur).(142)(143)(144) As these studies were also identified in the Cochrane review in Chapter 2 they will not be described in detail here.

One ongoing study was identified. The mAssist trial in South Africa randomised 469 women seeking medical abortion to text messaging or standard care. (145) The intervention comprised a series of text messages to support the abortion process (including information on PAFP) over a three-week period. The authors provisionally reported increased long-acting reversible contraception uptake at seven-weeks (21% vs. 13%).

The review identified a number of other mHealth contraception initiatives that have been launched and scaled up in low-income settings, but not subject to evaluation of contraceptive outcome measures, for example, Mobile for Reproductive Health (m4RH) and the Mobile Alliance for Maternal Action (MAMA).(146)(147) FamPlan is a Hotline in the Philippines that allows users to ask questions via text message.(148)

Examples of mobile phone applications included CycleTel (using the standard days method) and MyPill (for OC reminders).(149)(150)

The review concluded that *‘although a number of other initiatives using interventions delivered by mobile phone to increase contraception use have been launched and scaled up in low-income settings, to date, the effect of mHealth interventions on contraceptive uptake or adherence have not been reliably established’* and *‘no studies have formally reported mHealth PAFP interventions’* and that *‘there is therefore a need for more evidence on the effectiveness of mHealth interventions for contraception’*.

1.7 Aims and objectives

The aim of this research is to answer the broader research question: *Can interventions delivered by mobile phone increase contraception use?* The research has four main objectives:

1. Conduct a systematic review of interventions delivered by mobile phone for contraception: to complete a Cochrane review entitled *‘Mobile phone-based interventions for improving contraception use’*
2. Develop an intervention delivered by mobile phone to support PAFP in Cambodia
3. Evaluate the intervention with a randomised controlled trial including analysis of four and 12-month follow-up data
4. Conduct a mixed methods process evaluation

1.8 Thesis structure

The following research paper style thesis contains eight chapters including this chapter addressing the objectives of the thesis. The sequence of papers follows a logical

sequence starting with a literature review and progressing to the intervention development, trial protocol followed by the trial results and process evaluation. However, at times several papers were being worked on simultaneously, and some had longer peer-review processes than others meaning that the papers were published in a slightly different order than as presented.

Chapter 1 presents an introduction to the thesis and reviews relevant background literature, on contraception trends, theory and models to describe and predict contraceptive use, interventions delivered by mobile phone, behaviour change theory, and the aims and objectives of the thesis.

The next 6 chapters are research papers. The division of labour and contribution of others to these publications are stated in the research paper cover sheets for each chapter.

Chapter 2 is a systematic literature review of *'Mobile phone-based interventions for improving contraception use'* (Cochrane review). This chapter builds on the literature review conducted for my PhD upgrade as discussed in Section 1.6. After approaching the Cochrane fertility group to enquire whether I could conduct a Cochrane review on mobile phone-based interventions to increase contraception use, the provisional title was approved and published in 2012. The protocol was published in 2014 and the search strategy used for my PhD upgrade was broadened to include additional keywords, electronic databases and clinical trials registries. The review was conducted in accordance with Cochrane methodology with respect to data extraction on outcomes, assessment of bias and methodological quality, calculation of measures of effect, presentation of results and discussion using Revman software. The review was published in 2015 and included unpublished four-month follow up data from the

MOTIF trial (the full results including 12-month follow up are presented in Chapter 5).

The division of labour and contribution of others to this review are stated in the research paper cover sheet for Chapter 2. Although the protocol was a separate publication subject to peer review I have not included it in this thesis as the protocol was incorporated in to the methods section of the main review paper. In addition to the published Cochrane review, at the end of this chapter I have included a section on trials published subsequent to conducting the database searches in October 2014.

Chapter 3 is a research paper describing the intervention development for the MOTIF trial. Specifically this paper comprises reviews of relevant literatures, a case note review of clinic data, interviews and focus groups with women seeking abortion services and consultation with clinicians and local organisations implementing mHealth activities and presents a conceptual framework for the intervention. I presented the intervention development at the International Conference on Family Planning in Ethiopia in 2012 and this paper was subsequently prepared and accepted for publication after the conference.

Chapter 4 is a research paper outlining the trial protocol and a subsequent update publication describing some amendments that was submitted after my PhD upgrading seminar on 2nd April 2014. The papers provide detail on the study design, intervention, study hypothesis, sample size calculation, outcome measures, effect measures and proposed statistical analysis methods. Separately a detailed trial Statistical Analysis Plan was written and sealed prior to commencing data analysis (Appendix 4).

Chapter 5 is a research paper that presented the results of the MOTIF randomised controlled trial and includes data on baseline characteristics of participants, primary

and secondary outcomes collected at four and 12-month follow up, as well as subgroup and discontinuation figures for the 12-month follow up data.

In addition to the published trial paper, this chapter contains three additional analyses. First is some additional trial analysis, which includes pre-specified analyses that could not be included in the main trial paper due to word count limitations as well as exploratory analyses of the dynamics of contraception use over the post-abortion period. The aim of this analysis is to further understand the patterns of contraceptive use over the post-abortion period, in particular differences in uptake, discontinuation and switching between the intervention and control groups. Second is an overview of approaches to measuring adherence to effective contraceptive methods together with an analysis assessing the validity and reliability of self-report data on contraception use collected in the trial; also a pre-specified analysis that could not be included in the main trial paper due to word count limitations. Third is an exploratory analysis assessing factors associated with loss to follow-up in the trial and comparing how the result might have varied using different analysis methods such as multiple imputation.

Chapter 6 presents a quantitative process evaluation assessing response to the intervention using data collected during the intervention. Specifically this paper includes a descriptive analysis to assess participants' interaction with the intervention, and a logistic regression analyses to assess interaction with the intervention and subsequent contraception use. The paper assesses associations between baseline socio-demographic factors and interaction with the intervention considering the public health implications of the intervention. This paper is being reviewed by a peer-review journal as of August 2016.

Chapter 7 is a research paper reporting women's views and experiences of receiving the intervention. The study comprised 15 qualitative interviews conducted with women that received the intervention. The interviews were conducted in 2013-14 and briefly coded at the time and I undertook more thorough analysis in 2016. This paper identifies key themes regarding women's experiences receiving the intervention, and considers the mechanism of action reflecting on the theory and conceptual framework presented in Chapter 3, and considers how the intervention could be improved. The paper was submitted to a journal in September 2016.

In **Chapter 8** I summarise the main findings of the thesis and its overall strengths and limitations, discuss the meaning of the study and possible mechanisms of action in relation to other studies in the fields of contraception and interventions delivered by mobile phone, and finally discuss recommendations for practice and further research.

1.9 Ethics

The trial was conducted in accordance with the principles of Good Clinical Practice,⁽¹⁵¹⁾ and I attended an Introduction to Good Clinical Practice course at Imperial College in May 2012. Ethical approval was granted by the LSHTM ethics committee, the Marie Stopes International ethics committee and the Cambodia National Ethics Committee for Health Research (NECHR) for the formative research (Phase 1), the trial (Phase 2) and 12-month follow up (Phase 3).

- Phase 1 approvals: Cambodia NECHR (number: C2/23 NECHR); LSHTM (number: 6282); MSI (number: 013-12-FT-A)
- Phase 2 approvals: Cambodia NECHR (number: 0036 NECHR); LSHTM (number: 6378); MSI (number: 002-13-E)

- Phase 3 approvals: Cambodia NECHR (number: 0193 NECHR); LSHTM (number: 6378-01); MSI (number: 002-13-Am14)

The MOTIF trial is registered with ClinicalTrials.gov, number: NCT01823861.(152)

1.10 Study setting, collaborations and funding

The idea of using mobile phone communication to support contraception use originated from my time working in rural Cambodia as an international fellow to the National Health Service (NHS) 'Improving Global Health' scheme in 2008-9. During this time we aimed to improve healthcare services in Samlaut district in the rural North-West of Cambodia, supported by Maddox Jolie-Pitt (MJP) foundation.(153) In order to assess priorities we conducted a household survey asking what services people thought should be provided at their local health centre. Many of the women, and some men, requested improved contraception services as they had large families and didn't feel able to support more children. As a result we set up a basic family planning service from the local health post providing condoms, pills and injectables. However, several months later when we evaluated the service we discovered that many of the women had discontinued their contraception due to fear or experience of side-effects, for example amenorrhoea. My impression was that there was a lack of access to good quality health information in the rural areas with most women obtaining information about contraception from family or friends. At a later date it occurred to me that as most people had mobile phones, albeit simple ones, that this could be a way to communicate health information to populations in rural areas.

I approached the innovation and research teams at Marie Stopes International and Caroline Free (CF) at LSHTM with the idea of undertaking a PhD research project on

the topic of mHealth and contraception in late 2011. Following some initial exploratory discussions, in January 2012 I visited MSI country programmes in Kenya and Cambodia to discuss the possibility of collaborating on an application for an internal MSI Innovation fund project. Whilst both country programmes expressed an interest I decided to work with MSI Cambodia given my prior experience working in the country. Independently, Caroline Free and Thoai Ngo, then Head of Research at Marie Stopes International, had discussed developing an intervention delivered by mobile phone to support contraception use in South East Asia. The MOTIF project successfully obtained funding (£146,736) from the head office at MSI in London over a 15-month period from October 2012-December 2013. During this time I worked together with a Cambodian team comprising a project manager (Uk Vannak), two counsellors (Ly Sokhey and Sieklot Cheam) and four research assistants to develop, implement and evaluate a mobile phone-based intervention to support PAFP at four MSI clinics in Cambodia. I commenced my PhD at LSHTM, registering as a part-time student on 23rd November 2012. During October 2012 to March 2013 we conducted formative research to develop the intervention. My supervisor (CF) visited Cambodia during the week commencing 25th March 2013 and we had meetings with the team at MSI Cambodia as well as other organisations in Cambodia. We decided to collaborate with the InSTEDD South East Asia iLab as our tech partner to deliver the intervention as we considered their 'Verboice' voice-messaging product the best option for delivering a voice-based intervention. During March and April 2013 we further refined the intervention, obtained ethical approvals, hired additional research assistants and developed Standard Operating Procedures (SOPs) for the different team members. We recruited participants to the trial during May and September 2013. We conducted

four-month trial follow up during August 2013 and January 2014, having been granted a one-month no-cost extension. Qualitative interviews with women who had received the intervention were conducted between October 30th and November 23rd 2013.

I was awarded a three-year Medical Research Council Population Scientist Fellowship (grant code: MR/L012251/1) commencing 1st April 2014 that included costs for long-term trial follow-up and funded my time to conduct the quantitative and qualitative analyses, prepare publications and write up my PhD.

2. Mobile phone-based interventions for improving contraception use: a systematic review of randomised controlled trials

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS

SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	Cochrane Database of Systematic Reviews. Full citation as follows: Smith C, Gold J, Ngo TD, Sumpter C, Free C. Mobile phone-based interventions for improving contraception use. Cochrane Database of Systematic Reviews 2015, Issue 6. Art.No.: CD011159. DOI: 10.1002/14651858.CD011159.pub2.		
When was the work published?	Publication status and date: New, published in Issue 6, 2015. Review content assessed as up-to-date: 19 March 2015.		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	The copyright belongs to the Cochrane Collaboration. The work is not being included in its published format (it has been converted to Word format, tables and figures have been re-created, references have been changed to the Vancouver system as per the rest of the thesis). The copyright holder has given permission for this work to be included in the thesis (see Appendix 5)	Was the work subject to academic peer review?	Yes

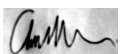
**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (published or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Myself and Caroline Free had the idea for the review. I undertook the search and selection process, including the construction and implementation of search and quality appraisal strategies. I contacted authors of papers to ask for additional information from selected papers. Myself and Colin Sumpter screened and selected studies and undertook data extraction (as two people are required to do this). Judy Gold commented on selection of studies. Judy Gold and Caroline Free commented on risk of bias and assessment of behaviour change techniques. I was responsible for conducting the statistical analysis, interpretation and drafting the manuscript. All of the review authors reviewed and commented on the review.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

Mobile phone-based interventions for improving contraception use (review)

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2.1 Abstract

Background

Contraception provides significant benefits for women's and children's health, yet an estimated 225 million women had an unmet need for modern contraceptive methods in 2014. Interventions delivered by mobile phone have been demonstrated to be effective in other health areas, but their effects on use of contraception have not been established.

Objectives

To assess the effects of mobile phone-based interventions for improving contraception use.

Search methods

We searched for randomised controlled trials (RCTs) of client-provider interventions delivered by mobile phone to improve contraception use compared with standard care or another intervention. We searched the electronic databases Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, Global Health, PsycINFO, POPLINE, Africa-Wide Information and Latin American Caribbean Health Sciences

Literature (LILACS) from January 1993 to October 2014, as well as clinical trials registries, online mHealth resources and abstracts from key conferences.

Selection criteria

Randomised controlled trials of mobile phone-based interventions to improve any form of contraception use amongst users or potential users of contraception. Outcome measures included uptake of contraception, measures of adherence, pregnancy and abortion.

Data collection and analysis

Two review authors independently screened titles and abstracts of studies retrieved using the search strategy and extracted data from the included studies. We calculated the Mantel-Haenszel risk ratio (RR) for dichotomous outcomes and the mean difference (MD) for continuous outcomes, together with 95% confidence intervals (CIs). Differences in interventions and outcome measures did not permit us to undertake meta-analysis.

Main results

Five RCTs met our inclusion criteria. Three trials aimed to improve adherence to a specific method of contraception amongst existing or new contraception users by comparing automated text message interventions versus standard care. Two trials aimed to improve both uptake and adherence, not limited to one method, in both users and non-users of contraception. No trials were at low risk of bias in all areas assessed.

One trial in the USA reported improved self reported oral contraceptive (OC) continuation at six months from an intervention comprising a range of uni-directional and interactive text messages (RR 1.19, 95% CI 1.05 to 1.35). One trial in Cambodia

reported increased self reported use of effective contraception at four months post abortion from an intervention comprising automated interactive voice messages and phone counsellor support (RR 1.39, 95% CI 1.17 to 1.66). One feasibility trial in the USA reported a lower mean number of days between scheduled and completed attendance for the first but not subsequent Depo-Provera appointments using clinic records from an intervention comprising reminders and healthy self management text messages (mean difference (MD) -8.60 days, 95% CI -16.74 to -0.46). Simple text message OC reminders had no effect on missed pills as assessed by electronic medication monitoring in a small trial in the USA (MD 0.5 missed pills, 95% CI -1.08 to 2.08). No effect on self reported contraception use was noted amongst isotretinoin users from an intervention that provided health information via two uni-directional text messages and mail (RR 1.26, 95% CI 0.84 to 1.89). One trial assessed potential adverse effects of the intervention and reported no evidence of road traffic accidents or domestic abuse.

Authors' conclusions

Our review provides limited evidence that interventions delivered by mobile phone can improve contraception use. Whilst evidence suggests that a series of interactive voice messages and counsellor support can improve post-abortion contraception, and that a mixture of uni-directional and interactive daily educational text messages can improve OC adherence, the cost-effectiveness and long-term effects of these interventions remain unknown. Further high-quality trials are required to robustly establish the effects of interventions delivered by mobile phone to improve contraception use.

2.2 Plain language summary

Interventions delivered by mobile phone to support client use of family

planning/contraception

Contraception - methods or devices used to prevent pregnancy - has significant benefits for women's and children's health. Despite these benefits, an estimated 225 million women in developing countries were not using a modern contraceptive method in 2014 despite wanting to avoid pregnancy. Expansion of mobile phone use in recent years has led to increased interest in healthcare delivery via mobile phone and the potential to deliver support wherever the person is located, whenever it is needed, and to reach populations with restricted access to services. Mobile phone-based interventions have been demonstrated to be effective in other health areas, but not yet in the field of contraception.

In 2014, we undertook computer searches for randomised trials evaluating mobile phone-based interventions to increase contraception use. We found five trials. Three trials used text messaging to support women in continuing to use a specific method of contraception. Two trials aimed to improve both uptake and continued use of contraception - one with voice and one with text messaging. Our review provides limited evidence that interventions delivered by mobile phone improve contraception use. One trial in the USA reported that women were more likely to continue to take the contraceptive pill from an intervention comprising a range of educational text messages. One trial in Cambodia reported increased use of contraception at four months post abortion from an intervention comprising voice messages and phone counsellor support. Another trial in the USA reported improved attendance for the first but not subsequent contraceptive injection appointments from an intervention comprising reminders and healthy self management text messages. Simple text message contraceptive pill reminders did not reduce missed pills in a small trial in the

USA. No difference in contraception use was reported amongst users of isotretinoin (a drug used for acne) from an intervention that provided health information via text messages and mail.

In conclusion, evidence indicates that a series of voice messages and counsellor support can improve contraception amongst women seeking abortion services not wanting to get pregnant again at the current time, and data suggest that daily educational text messages can improve continued use of the contraceptive pill. However, the cost value and long-term effectiveness of these interventions remain unknown. More good quality trials are needed to establish the effectiveness of interventions delivered by mobile phone to increase contraception use.

2.3 Background

Rapid expansion in the use of mobile phones in recent years has had a dramatic impact on interpersonal communication. Within the health domain, phone calls, text messages and smartphone applications offer new means of communication between service providers and clients. This review focuses on interventions delivered by mobile phone to improve contraception use.

Description of the condition

Contraception - methods or devices used to prevent pregnancy - provides significant benefits for women's and children's health. Use of contraception prevents unintended pregnancies, reduces abortions and maternal deaths and can improve perinatal outcomes and child survival by widening the interval between successive pregnancies.(1) Contraception also confers substantial social and economic benefits such as improved educational and employment opportunities for women, leading to increasing family savings and economic growth.(2)

Despite these benefits, the unmet need for contraception is significant. Unmet need can be defined as women not using a modern contraceptive method despite wanting to wait two or more years to give birth, or wanting no more children.(154) The total number of women with unmet need was estimated to be 225 million in 2014.(155) Women report not using contraception for many reasons. The most common reasons for non-use are concerns about health and side effects of methods.(16)(87)(3) Other important barriers include lack of access to supplies and services, as well as factors outside the health system such as women's lack of education or empowerment.(155) If the unmet need for modern methods of contraception were met amongst women in developing countries, the number of unintended pregnancies would be reduced by 52 million per year. This reduction in unintended pregnancies would avert an estimated 24 million abortions (of which around half would be unsafe), 70,000 maternal deaths and 500,000 newborn deaths.(155)

Description of the intervention

The past decade has seen rapid expansion in the delivery of health-care interventions via mobile phone.(112) Interventions delivered by mobile phone have been designed to improve health outcomes for individuals needing acute and chronic disease management and to facilitate health promotion. These interventions may be designed to improve medication adherence, encourage appointment attendance or promote behaviour change.(115)(156)(124) Interventions delivered by mobile phone have also provided a novel means of delivering patient test results.(157)

Interventions can utilise different functions of mobile phones such as text messages, voice messages, videos and applications; may involve one-direction or two-way (interactive) communication;(114)(116) and can employ single functions or combined

functions of mobile phones such as interactive text message-based support or voice messaging combined with telephone counselling. Interventions delivered by mobile phone to improve contraception use could be provided as an adjunct or alternative to face-to-face services and, for non-users of contraception, could aim to increase uptake of contraception. Interventions for existing contraceptive users could aim to improve adherence to contraception, reduce discontinuation of contraceptives or encourage switching rather than stopping contraceptives if the individual experiences side effects.

How the intervention might work

Interventions delivered by mobile phone offer potential advantages over face-to-face or landline phone healthcare delivery, as support can be delivered wherever the person is located, and whenever it is needed.⁽¹⁵⁸⁾ Such interventions can facilitate confidential access to healthcare information amongst younger populations, who are regular mobile phone users.⁽¹⁵⁹⁾⁽¹²⁴⁾⁽¹⁶⁰⁾

Furthermore, these interventions have the potential to reach rural populations, for whom geographical distances can restrict access to services.⁽¹⁶¹⁾ Intervention content could include information, pill or appointment reminders and/or content designed to increase or maintain motivation to use contraception. Behaviour change techniques used in face-to-face interventions can be modified for delivery by mobile phone.⁽¹¹⁵⁾

Interventions could utilise a range of behaviour change techniques, such as encouraging women to make a clear plan about when, where and how they will use contraception (goal setting).⁽¹⁰⁴⁾ Multi-faceted interventions that address a wide range of barriers to contraception use could be more effective than those targeting single barriers to use. Existing adherence research suggests that multi-faceted interventions can be effective but uni-faceted interventions provide at best modest

benefits.(134) Similarly, no evidence indicates that medication reminders delivered by mobile phone have benefits (pooled risk ratio 1.00, 95% confidence interval 0.77 to 1.30),(115) whilst trials of more complex interventions to improve adherence to antiretroviral medication report benefits.(115)(127)

Several potential risks are associated with using mobile phones to improve contraception use. Road traffic accidents are the only adverse health effect of cell phone use for which evidence is available.(162)(163)(164) However, in the often sensitive context of contraception, the potential for physical or psychological adverse effects could arise as a result if other people access intervention content when mobile phones are shared. Further risk relates to the opportunity cost of investing substantial resources in developing a technologically focused intervention with most likely a moderate impact, instead of investing in alternative approaches. Additional challenges related to implementation of interventions delivered by mobile phone include limited literacy of target populations, incomplete network coverage, phone number switching and risk of incomplete data input and inaccurate data acted upon.(141)(165)

Why it is important to do this review

Interventions delivered by mobile phone have been demonstrated to be effective in other areas such as smoking cessation.(125)(123)(124) When interventions delivered by mobile phone have been shown to be effective, they have also been shown to be highly cost-effective.(126) However, evidence related to interventions delivered by mobile phone for contraception is more limited.

In recent years, interest in interventions delivered by mobile phone has been growing, as reflected in a number of mobile phone-based contraception initiatives that have been launched, and in some cases scaled up, such as Mobile Technology for Improved

Family Planning (MOTIF), mAssist, Mobile for Reproductive Health (m4RH), CycleTel and Mobile Alliance for Maternal Action (MAMA).(166)(149)(146)(147)(167) Although these initiatives seem promising, each uses different intervention and evaluation approaches, and the effect of interventions delivered by mobile phone on contraception has not been reliably established. Therefore a review of interventions delivered by mobile phone for contraception is timely.

Objectives

To assess the effects of mobile phone-based interventions for improving contraception use.

2.4 Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs).

Types of participants

Eligible participants were men or women of reproductive age who were users or potential users of contraceptive methods. We included studies in all settings (e.g. primary care settings, outpatient settings, community settings, hospital settings). We did not exclude studies according to the types of healthcare providers who participated (e.g. doctor, nurse, allied staff).

Types of interventions

We included studies that examined any type of client-provider intervention delivered by mobile phone designed to improve use of contraception compared with standard delivery of care or another intervention. We included interventions directed at both

users and non-users of contraception. Eligible interventions included those designed to do the following.

- Improve uptake of contraception (including post-abortion and post-partum contraception).
- Promote specific methods of contraception.
- Improve adherence to contraception (e.g. interventions to support individuals experiencing side effects, reduce discontinuation, ensure safe method switching or send pill or appointment reminders).

We included interventions aimed at mobile phone users delivered by mobile phone that included some degree of automation, for example, text message, voice message and applications. We excluded trials in which mobile phones were used for two-way voice communication (as a phone) alone, in keeping with previous reviews of mobile phone-based interventions.⁽¹²³⁾⁽¹²⁴⁾ Web-based interventions often can be accessed on mobile phones, as well as through other platforms, but in practice can be difficult to access via mobile phone unless they are adapted for mobile phone use. We excluded web-based interventions unless study authors stated that they had been intended or adapted for mobile phone users. We excluded trials that focused only on preventing sexually transmitted disease rather than providing contraception.

Types of outcome measures

Primary outcomes

- Uptake of contraception (including post-abortion and post-partum contraception).

- Uptake of a specific method of contraception (e.g. a long-acting method⁴).
- Adherence to contraceptive method (e.g. number of missed pills, attendance for repeat injection).
- Safe method switching (e.g. from one effective method to another with no gap).
- Discontinuation of contraception.
- Pregnancy or abortion (objectively measured or self reported).

Secondary outcomes

- Road traffic accidents - the only adverse health effect of cell phone use for which evidence is available.(164)
- Any physical or psychological effect reported.

We included studies that assessed any form of contraceptive use and trials assessing a range of outcome measures related to contraceptive use, including uptake of contraception, selection of a specific method, use of measures of adherence (including discontinuation and safe switching), pregnancy or abortion.

We considered sustained and point prevalence measures as well as subjective (self reported) and objective (e.g. biochemically verified, electronic medication monitors used, clinical examination performed) assessment of contraception use.

Contraceptive methods can be classified in different ways. Contraception can be classed as modern (e.g. condom, oral contraceptive pills, injectables, intrauterine device, implant, emergency contraception) or traditional (e.g. rhythm or periodic abstinence, withdrawal).(3)(6) Furthermore, distinctions can be made between hormonal and non-hormonal methods, and between short-acting and long-acting or

⁴ The definition of 'long-acting' method would be based on the study author's description

permanent methods. The World Health Organization (WHO) classifies methods according to effectiveness on the basis of estimated rates of unintended pregnancy per 100 women per year.(6) For this review, we define effective modern methods as those associated with < 10% 12-month pregnancy rates; commonly used methods include oral contraceptive, injectable, implant, intrauterine device and permanent methods.

Search methods for identification of studies

Electronic searches

We searched the following electronic databases between 6 and 9 October 2014.

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE using Ovid
- EMBASE using Ovid
- Global Health using Ovid
- PsycINFO using Ovid
- Population Information Online (POPLINE)
- Africa-Wide Information
- Latin American Caribbean Health Sciences Literature (LILACS)

We included Africa-Wide Information and LILACS, given the proliferation of mobile phone-based initiatives in low- and middle-income regions. We searched for recent clinical trials separately via the WHO International Clinical Trials Registry Platform (www.who.int/trialsearch) and Current Controlled Trials (www.controlled-trials.com), which included clinicaltrials.gov.

We searched for studies published in all languages from January 1993 until the present (i.e. the date of the search), as the first text message was sent in December 1992.(108)

We presented in Table 9 the electronic database search strategies that we used.

Searching other resources

We wrote to the contact investigators of included studies to request additional information about studies when required, as well as information about trials not discovered in our search. To identify completed or on-going studies that had not been identified in the electronic searches, we reviewed abstracts from the mHealth summit, Women Deliver and the International Conference on Family Planning. We also reviewed online repositories of mHealth interventions including Health Unbound, Royal Tropical Institute, mHealthinfo, K4Health and mHealth Evidence.

Data collection and analysis

Selection of studies

We exported search results into a software programme for bibliographic citation management and excluded duplicate references. Two review authors independently screened titles and abstracts of studies retrieved using the search strategy. We retrieved full articles for further assessment if the information given suggested that the study (1) included participants who were users or potential users of contraception, (2) compared use of an intervention delivered by mobile phone versus routine standard of care or another intervention or (3) assessed one or more relevant outcome measures. If we had any doubt regarding these criteria from the information provided in the title and abstract, we retrieved the full article for clarification. Two review authors retrieved the full text of potentially eligible studies and independently assessed them for eligibility, with disagreements resolved through discussion with a third review author.

Data extraction and management

Two review authors independently extracted the following data from the included studies using a standardised data extraction form.

- General information: title, study authors, complete citation, publication status, date published, language, review author information, date reviewed, sponsoring, setting.
- Study characteristics: study design, aim of study, duration, participant recruitment, sampling, inclusion and exclusion criteria including numbers screened and eligible, randomisation, allocation concealment, method of allocation concealment, blinding, informed consent, power analysis.
- Risk of bias (see Table 4).
- Participants: description, geographical location, setting, number, age, ethnicity, socioeconomic status distribution.
- Providers: description, geographical location, setting.
- Intervention: description, aim of intervention, any behaviour change intervention (according to the study authors' description and our assessment according to an established typology of behaviour change techniques),(104) duration, frequency and 'dose', control or placebo intervention, technical specifications including device and mobile phone functions used (e.g. text message, voice message), message content, co-interventions.
- Outcomes: outcomes as specified above, other outcomes assessed, length of follow-up, methods used to assess outcomes, completeness of outcome data, follow-up for non-respondents, adverse events.
- Results: outcomes and times of assessment, intention-to- treat analysis (when all randomly assigned participants are included, irrespective of what happened

subsequently).(168)

Review authors discussed disagreements and resolved them through discussion with a third review author as necessary.

Assessment of risk of bias in included studies

Review authors assessed studies for risk of bias in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions*,(169) across the following domains: random sequence generation, allocation concealment, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other potential biases. Two review authors independently assessed risk of bias, discussed disagreements and resolved them through discussion with a third review author as necessary. We used a standardised form to guide assessment of risk of bias, and judged each domain as having 'high', 'low' or 'unclear' risk. We presented all included studies by study type and risk of bias level. As required, we contacted study authors to ask for additional information. We presented the results of the risk of bias assessment in tables in Table 4, and as a systematic narrative description.

Measures of treatment effect

We used risk ratios (RRs) as measures of treatment effect for dichotomous outcomes, and mean differences (MDs) for continuous outcomes. We reported 95% confidence intervals (CIs) with all measures of effect.

Unit of analysis issues

We planned to take into account unit of analysis issues resulting from cluster RCTs, repeated measurements and studies with more than one treatment group and, if appropriate, to analyse data in accordance with recommendations of the *Cochrane Handbook for Systematic Reviews of Interventions*.(169) However, we did not identify

any unit of analysis issues.

Dealing with missing data

We planned to assess missing data on individuals as guided by the *Cochrane Handbook for Systematic Reviews of Interventions*. We would ignore missing data if they were assumed to be missing at random. If feasible, we planned to contact study authors to ask for missing data when it was assumed that they were not missing at random, for example, if some randomly assigned participants were excluded from analyses. If feasible, we planned to use statistical techniques, as appropriate to each study, to impute missing data to enable an available case or intention-to-treat analysis.⁽¹⁶⁹⁾ For missing summary data, if feasible, we planned to approximate the correct analyses to impute missing summary statistics (e.g. standard deviations), in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions*.⁽¹⁶⁹⁾

Assessment of heterogeneity

We did not undertake a meta-analysis, as the studies identified were so different in terms of both interventions and outcome measures.

Assessment of reporting biases

We did not assess reporting biases statistically, as the studies identified were so different in terms of both interventions and outcome measures.

Data synthesis

We conducted statistical analysis according to the guidelines provided in the *Cochrane Handbook for Systematic Reviews of Interventions*.⁽¹⁶⁹⁾ We presented a narrative overview of the findings, together with tabular summaries of extracted data. Differences in study populations, interventions, comparators and outcomes precluded

us from pooling data across studies to estimate summary effect sizes. We used the Mantel-Haenszel risk ratio fixed-effect model for dichotomous data and mean differences (MDs) for continuous data. When meta-analysis was not possible, we presented summary and descriptive statistics.

We summarised the quality of evidence provided by studies using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach while considering factors that decrease the quality level of a body of evidence.(169)

Randomised controlled trials were considered of high quality and were downgraded by one level (serious) or two levels (very serious) for each of the following reasons.

- Limitations in design and implementation (e.g. lack of blinding, large losses to follow-up).
- Indirectness of evidence (e.g. trials that meet eligibility criteria but address a restricted version of the main review question in terms of population, intervention, comparator or outcomes).
- Unexplained heterogeneity or inconsistency of results (e.g. when heterogeneity exists and affects interpretation of results, but study authors fail to identify a plausible explanation).
- Imprecision of results (e.g. when studies include few participants and thus have wide confidence intervals).
- High probability of publication bias (e.g. if investigators failed to report studies or outcomes on the basis of results).

Subgroup analysis and investigation of heterogeneity

We planned to perform subgroup analyses if one of the primary outcome parameters demonstrated statistically significant differences (at P value < 0.01) between

treatment groups. These would have included meta-analyses on studies amongst specific populations, specifically, younger versus older women; high-income versus low-income settings; and post delivery versus post abortion versus general clinic attendees. However, we did not identify studies appropriate for this subgroup analysis. We did not identify studies promoting traditional contraceptive methods; therefore we did not undertake the planned subgroup analysis including only modern methods, or methods considered effective or very effective by the WHO.(6)

Sensitivity analysis

We did not identify a sufficient number of studies to perform the following sensitivity analyses.

- Repeating the analysis while excluding unpublished studies to investigate potential publication bias resulting from publication or non-publication of research findings, depending on the nature and direction of the results.(169)
- Repeating the analysis while taking account of risk of bias of included studies, as specified above.

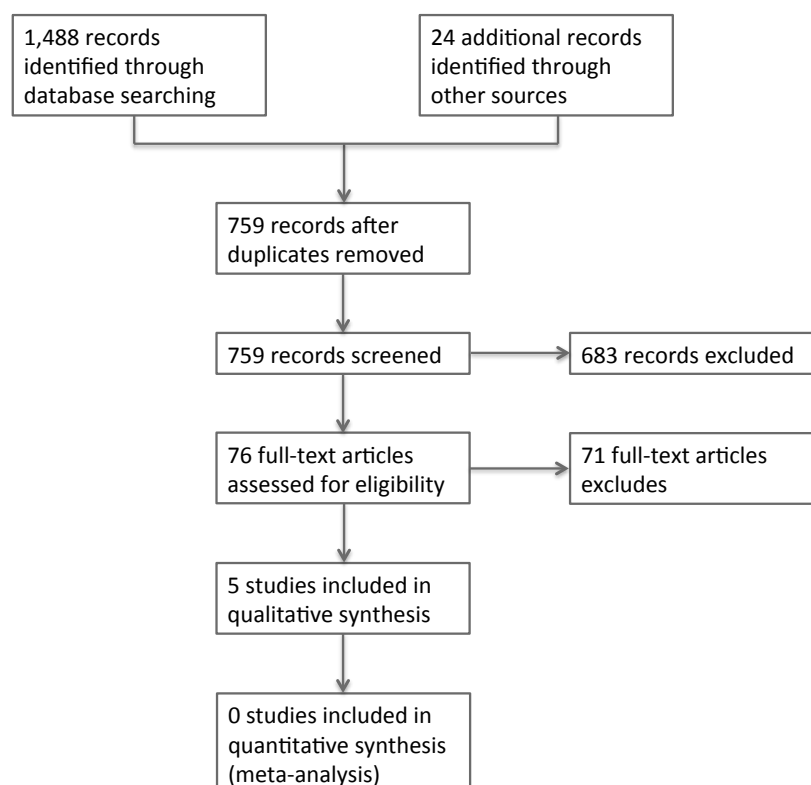
2.5 Results

Description of studies

Results of the search

We conducted searches during October 2014 and produced 759 records after removing duplicates. We discarded 683 records after review of titles and abstracts. We assessed 76 full-text articles for eligibility. See Figure 5 for the study flowchart.

Figure 5: Study flow diagram



We identified four on-going studies (see Table 3).

Table 3: Characteristics of on-going studies

Johnson 2014	
Trial name or title	Randomised Controlled Trial Evaluation of m4RH
Methods	Randomised Controlled Trial
Participants	Users or potential users of contraception who registered for m4RH with a text message
Interventions	m4RH text messaging intervention
Outcomes	Contraceptive knowledge and use
Starting date	2014
Contact information	Pamela Riley: Pamela.riley@abtassoc.com
Notes	
NCT01401816	
Trial name or title	Advanced Provision of Emergency Contraception: Utilising Technology to Increase Prescription Fill Rates
Methods	Pilot randomised controlled trial (n = 60) of a text messaging intervention
Participants	Sexually active female adolescents 13 to 21 years of age who have been provided with a prescription for emergency contraception
Interventions	Follow-up text message on the phone to remind them to fill the prescription
Outcomes	Primary outcome: prescription fill rates. Secondary outcomes: sexual activity, contraception use, risk of pregnancy, knowledge of emergency contraception
Starting date	July 2011
Contact information	Tracey.a.wilkinson@gmail.com

Notes

NCT01545609

Trial name or title	A Text Message Support System for Effective Continuation of a Birth Control Method in Female Adolescents: 'BC 2U': NCT01545609
Methods	Randomised controlled trial (n = 220)
Participants	Inner city, minority adolescent females (15 to 19 years of age), English speaking, owner of a working cell phone, wanting to start a birth control method and not on a method for the preceding 3 months, no contraindications to initiating a birth control method
Interventions	Intervention: tailored text messages about their method of contraception
Outcomes	Primary outcome: continuation of a birth control method at 4 months. Secondary outcomes: change in birth control method used, pregnancy
Starting date	March 2012
Contact information	Jf2815@cumc.columbia.edu
Notes	Expect publication in 2015

NCT02093884

Trial name or title	A Pilot Study Using Text Messaging to Communicate With Adolescent Females in the Pediatric Emergency Department T2
Methods	Pilot randomised controlled trial (n = 100) using text messaging vs. standard care to increase contraceptive use
Participants	Adolescent females at high risk of pregnancy in the emergency department who are potential users of contraception (high risk of pregnancy is defined as sexually active in the past 3 months and did not use effective contraception at last intercourse and is not on it now)
Interventions	Intervention: 3 months of 31 random text messages developed from qualitative interviews. Standard care: paper wallet card advertising family planning clinic
Outcomes	Primary outcome: initiation of highly effective contraception. Secondary outcomes: follow-up, condom use, contraception counselling
Starting date	2014
Contact information	Lauren S Chernick: lc2243@cumc.columbia.edu
Notes	Expect publication in 2015

Included studies

We identified five randomised controlled trials that fulfilled the inclusion criteria

(Castano 2012; Hou 2010; Smith 2014; Trent 2013; Tsur 2008) (see Table

4).(142)(143)(170)(144)(171) Three trials were conducted in the USA (Castano 2012; Hou 2010; Trent 2013), one in Israel (Tsur 2008) and one in Cambodia (Smith 2014).

One was multi-site (Smith 2014), and four were single-site (Castano 2012; Hou 2010; Trent 2013; Tsur 2008). Three trials recruited participants from urban clinics (Castano 2012; Hou 2010; Trent 2013), one trial from clinics serving both urban and rural

populations (Smith 2014) and one trial from individuals who phoned an advice line (Tsur 2008). All trials included only female participants. Two trials focused on youth populations (Castano 2012; Trent 2013), and three included younger and older women of reproductive age (Hou 2010; Smith 2014; Tsur 2008). Two trials recruited new users of OC (Castano 2012; Hou 2010), one recruited existing injectable users (Trent 2013) and two recruited both users and non-users of contraception (Smith 2014; Tsur 2008).

Table 4: Characteristics of included studies

Castano 2012	
Methods	Individual randomised controlled trial. Estimated 6-month continuation rate in the control group of 40% and that a sample size of 960 would be required to detect a 10% change in OC continuation, with 80% power at a 0.05 level of significance, anticipating 15% loss to follow-up
Participants	962 sexually active females 13 to 25 years of age electing to use OC at a Planned Parenthood family planning health centre in downtown Brooklyn, New York, USA
Interventions	Control group: routine care including contraceptive counselling by staff and an educational information handout detailing use, effectiveness, benefits and risks Intervention group: routine care plus automated mobile phone-based intervention comprising 180 daily text messages aiming to improve OC continuation. This included an introductory message, 3 reminders of how to change contact information or message time, 47 individual educational messages, repeated up to 4 times, which incorporated 6 domains of OC knowledge (risks, benefits, side effects, use, effectiveness and mechanisms of action), 12 two-way messages for quality control and a final message. Intervention duration was 180 days
Outcomes	Primary outcome: self reported OC continuation (participant had taken OC within previous 7 days). Secondary outcomes: missed pills, interruptions in OC use > 7 days, use of OC at last sexual intercourse. All outcomes assessed by phone 6 months after enrolment
Behaviour change techniques	As defined by study authors: The educational messages incorporated 6 domains of OC knowledge: risks, benefits, side effects, use, effectiveness and mechanisms of action According to Abraham and Michie's typology: 4 behaviour change techniques used (see Table 5)
Notes	Loss to follow-up: 28% in the intervention group and 30% in the control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table used to generate the sequence
Allocation concealment (selection bias)	Low risk	Sequentially numbered, opaque, sealed envelopes used
Blinding of participants and	High risk	No blinding possible; outcome may have been influenced by lack of blinding

personnel (performance bias). All outcomes		
Blinding of outcome assessment (detection bias). All outcomes	High risk	Outcome assessors not blinded, as participants were asked about satisfaction with the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Main reason for incomplete data unlikely to be related to outcome
Selective reporting (reporting bias)	Unclear risk	Primary outcome of contraceptive continuation stated in the clinicaltrials.gov entry but insufficient detail on pre-specified measurements
Other bias	High risk	Possibility of detection (social desirability or recall) bias with self report measures of contraception use

Hou 2010

Methods	Individual randomised controlled trial. Estimated an average of 2.6 missed pills per cycle in the control group, and that a sample size of 68 would be required to detect a 1.6 pill improvement with standard deviation of 2 pills, with 90% power at a 0.05 level of significance, anticipating 15% loss to follow-up	
Participants	103 women enrolled to the study and 82 randomly assigned after a 1 month run-in period. 82 sexually active females electing to start using OC, seeking care at Planned Parenthood League of Massachusetts, USA. Mean age of 22 years (range 18 to 31)	
Interventions	Control group: routine care according to standard clinic protocol (not stated) during 1 month run-in period. Women in the control group did not receive text message reminders Study authors reported a high rate of reminder system use in the control group, particularly electronic systems such as cell phone alarms that mimicked the study intervention. Intervention group: routine care according to standard clinic protocol (not stated) during 1 month run-in period plus an automated daily text message aiming to improve OC adherence, "Please remember to take your birth control pill," sent at a designated time chosen by the participant over the 3 month study period	
Outcomes	Number of missed pills per cycle (assessed over 3 months) assessed with electronic monitoring device and patient diary	
Behaviour change techniques	As defined by study authors: not described According to Abraham and Michie's typology: 3 behaviour change techniques used (see Table 5)	
Notes	Loss to follow-up: 12% intervention and 10% control	

Risk of bias

Bias	Authors' judgment	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Sequentially numbered, opaque, sealed envelopes
Blinding of participants and personnel (performance bias).	High risk	No blinding possible; outcome may have been influenced by lack of blinding. Increased use of reminders in the control group suggests that allocation to intervention or control group may have altered behaviour

All outcomes		
Blinding of outcome assessment (detection bias). All outcomes	Low risk	Investigator blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reason for missing data (mechanical and technological issues) unlikely to be related to true outcome
Selective reporting (reporting bias)	Unclear risk	Primary and secondary outcomes stated in the clinicaltrials.gov entry, but insufficient detail on pre-specified measurements and subgroup analyses
Other bias	Low risk	Study appears to be free of other sources of bias (electronic medication monitor used to assess outcome)

Smith 2014

Methods	Individual randomised controlled trial. Estimated that use of effective contraception at 4 months would be 35% in the control group, and a sample size of 500 would be required to detect a 13% improvement in contraceptive use, with 90% power at a 0.05 level of significance	
Participants	500 participants; females 18 years of age or older, with a mobile phone primarily for their own use, reporting not wanting to be pregnant, willing to receive automated voice messages related to contraception, attending for induced abortion at 4 Marie Stopes International clinics in Cambodia	
Interventions	Control group: routine care, which included post-abortion family planning counselling at the clinic in accordance with national guidelines, the offer of a clinic follow-up appointment, the clinic phone number and the Hotline number operated by counsellors at MSI Cambodia Intervention group: routine care plus a mobile phone-based intervention aiming to improve uptake and adherence comprising 6 automated, interactive voice messages, counsellor delivered phone support according to response to messages and additional reminder messages for OC or injectable users	
Outcomes	Primary outcome: self reported effective contraception use at 4 months post abortion. Secondary outcomes: use of long-acting contraception (intrauterine device, implant, permanent method), repeat pregnancy, abortion, contraceptive use over the 4 month post-abortion period > 80%, road traffic accident and domestic abuse. All outcomes assessed by phone at 4 months (12 month follow-up is planned)	
Behaviour change techniques	As defined by study authors: Phone calls aimed to support contraceptive use by addressing participants' <i>capability</i> to use contraception by providing individualised information on a range of contraceptive methods, <i>opportunity</i> to use contraception (e.g. informing participants where they could access specific methods near to their residence) and <i>motivation</i> by re-enforcing the benefits of contraception use. According to Abraham and Michie's typology: 5 behaviour change techniques used (see Table 5)	
Notes	Loss to follow-up: 15% in the intervention group and 12% in the control group.	

Risk of bias

Bias	Authors' judgement	Support for judgment
Random sequence generation (selection bias)	Low risk	Computer-based randomisation programme used
Allocation concealment	Low risk	Web-based allocation performed after enrolment

(selection bias)		
Blinding of participants and personnel (performance bias). All outcomes	High risk	No blinding possible; outcome may have been influenced by lack of blinding
Blinding of outcome assessment (detection bias). All outcomes	Low risk	Researchers who undertook data collection and analysis were masked to treatment allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups. Reasons for missing data unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Study's pre-specified (primary and secondary) outcomes have been reported as pre-specified in the published study protocol
Other bias	High risk	Possibility of detection (social desirability or recall) bias with self report measures of contraception use

Trent 2013

Methods	Pilot individual randomised controlled trial (primarily a feasibility and acceptability trial)
Participants	100 female adolescents (13 to 21 years of age) recruited from an urban academic practice in a high teen and unplanned pregnancy prevalence community in the USA, currently using Depo-Provera, with a cell phone with text messaging capability for personal use. Most participants were African American and resided in low income, single parent, mother-headed households
Interventions	Control group: clinic protocol for standard care, which included participant-initiated support and clinical nursing outreach for missed appointments Intervention group: routine care plus automated intervention aimed to improve follow-up Depo-Provera clinic attendance and comprised a welcome message, daily text appointment reminders starting 72 hours before the clinic visit with the option to cease messages by responding (yes or no) with their plans to attend the visit. Intervention adolescents also received prescheduled health messages over the course of the 3 month enrolment period regarding condom use for STI prevention, healthy weight management, encouragement to call the nurse for problems and an STI screening reminder. All message signatures indicated that they were from the nurse case manager to build relationships with the clinical team
Outcomes	Primary outcome: days between next scheduled appointment and attendance for Depo-Provera injection over 3 cycles (9 months). Secondary outcome: on-time appointment for Depo-Provera injection over 3 cycles (9 months)
Behaviour change techniques	As defined by study authors: not described According to Abraham and Michie's typology: 2 behaviour change techniques used (see Table 5)
Notes	Information from abstract and additional communication with investigator. Full text not yet published Loss to follow-up: 12% in the intervention group and 14% in the control group

Risk of bias

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	Randomisation by permitted block design (according to investigator's communication)
Allocation	Low risk	Allocation sealed in envelope for nurse until informed consent

concealment (selection bias)		to participate (according to investigator's communication)
Blinding of participants and personnel (performance bias). All outcomes	High risk	No blinding possible; outcome may have been influenced by lack of blinding
Blinding of outcome assessment (detection bias). All outcomes	Low risk	PI blinded to allocation (according to investigators' communication)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups. Reasons for missing data unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Primary outcome pre-specified in the clinicaltrials.gov record
Other bias	Low risk	Study appears to be free of other sources of bias
Tsur 2008		
Methods	Individual randomised controlled trial. Estimated that use of contraception would be 50% in the control group, and a sample size of 100 would be required to detect 30% improvement in contraceptive use, with 80% power at a 0.05 level of significance	
Participants	108 females of reproductive age (16 to 45 years of age), some users and some not users of contraception, using or planning to use isotretinoin (a drug for acne), who phoned the Drug Consultation Centre at Assaf Harofeh Medical Center in Israel seeking advice regarding isotretinoin	
Interventions	Control group: Routine care comprised information on Isotretinoin including contraceptive use only during the initial interview. Intervention group: automated intervention aimed to increase contraception use and comprised routine care plus additional information about teratogenic risk and the importance of contraceptive use in mailed written form and by text messages sent to cellular phones 1 month and 2 months after the initial call	
Outcomes	Primary outcome: contraceptive use in women taking isotretinoin (methods of contraception not stated). Secondary outcomes: use of 2 contraceptives, sexual activity, contraceptive use amongst sexually active participants. All outcomes assessed by phone call at 3 months	
Behaviour change techniques	As defined by study authors: not described According to Abraham and Michie's typology: 2 behaviour change techniques used (see Table 5)	
Notes	5 participants (5%) lost to follow-up at 3 months and not included in the final analysis. Differential loss to follow-up between intervention and control groups not stated	

Risk of bias

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers kept in sealed envelopes
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not described in adequate detail. Sealed envelopes used, but unclear whether they were sequentially numbered and opaque

Blinding of participants and personnel (performance bias). All outcomes	High risk	No blinding possible; outcome may have been influenced by lack of blinding
Blinding of outcome assessment (detection bias). All outcomes	Unclear risk	Insufficient information on whether outcome assessors were aware of allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups
Selective reporting (reporting bias)	Unclear risk	Study protocol not available. The primary outcome is reported using measurements that were not pre-specified in the Methods section of the paper
Other bias	High risk	Possibility of detection (social desirability) bias with self report measures of contraception use

OC: oral contraceptive

STI: sexually transmitted infection

Interventions

Three trials aimed to improve adherence to a specific method of contraception by existing or new contraception users, comparing automated text message interventions versus standard care. Castano 2012 in the USA randomly assigned 962 new OC users 13 to 25 years of age; 480 to mobile phone text messaging and 482 to standard care. The intervention aimed to improve OC continuation and comprised a range of daily uni-directional and interactive educational text messages (e.g. *“The pill improves anaemia”*) for 180 days, in addition to standard care (face-to-face counselling and written educational hand-out).(142) Hou 2010 in the USA randomly assigned 82 new OC users between 18 and 31 years of age: 41 to mobile phone text messaging and 41 to standard care. The intervention aimed to improve OC adherence and comprised a daily text message, *“Please remember to take your birth control pill”*, sent at a designated time over the three-month study period.(143) Trent 2013 in the USA randomly assigned 100 current Depo-Provera users between 13 and 21 years of age to

mobile phone text messaging or standard care. The intervention aimed to improve follow-up Depo-Provera clinic attendance and comprised a welcome message, daily text appointment reminders starting 72 hours before the clinic visit and healthy self management messages sent over the course of the three-month enrolment period.(171)

Two trials aimed to improve both uptake and adherence, not limited to one method, in both users and non-users of contraception. Smith 2014 in Cambodia randomly assigned 500 women >18 years of age seeking abortion services who reported not wanting to get pregnant again at the current time: 249 to a semi automated intervention delivered by mobile phone and 251 to standard care. The intervention aimed to increase uptake and adherence to effective contraception (OC, injectable, implant, intrauterine device (IUD) and permanent methods) and comprised six interactive voice messages, counsellor-delivered phone support according to the response to messages and additional reminder messages for OC or injectable users.(170) Tsur 2008 in Israel randomly assigned 108 women of reproductive age (16 to 45 years of age) using isotretinoin (an acne treatment that is contraindicated in pregnancy): 50 to mobile phone text messaging and 58 to standard care. The intervention was automated and comprised two text messages (at one month and two months) together with information sent via mail, in addition to standard care (information given once during a phone interview).(144)

One of the five trials provided limited details of the intervention (Tsur 2008). No trials reported using a particular behavioural theory to underpin the intervention. Smith 2014 reported a conceptual framework for the intervention in the study protocol.(167) The maximum number of behaviour change techniques according to our assessment

using Abrahams and Michie’s typology, (104) for any intervention was six, and the median was three. The most commonly used behaviour change techniques were the following: provide information about behaviour-health link (four interventions), provide information on consequences (three interventions) and provide instruction (three interventions) and prompt practice (three interventions). Behavioural change techniques identified by our assessment are found in Table 5.

Table 5: Behaviour techniques used in interventions

Behaviour change technique	Studies
1. Provide information about behaviour-health link	Castano 2012 (e.g. “The pill improves anaemia”); Smith 2014 (e.g. information about amenorrhoea); Trent 2013 (healthy self management messages); Tsur 2008 (informed about importance of contraceptive use)
2. Provide information on consequences	Castano 2012 (“The pill is very effective at preventing pregnancy”); Smith 2014 (e.g. “contraceptive methods are an effective and safe way to prevent unintended pregnancy”); Tsur 2008 (informed about teratogenic risk)
3. Provide information about others’ approval	
4. Prompt intention formation	
5. Prompt barrier identification	Smith 2014 (If client received a phone call, counsellors provided reassurance regarding side effects as per conceptual framework reported in the study protocol)
6. Provide general encouragement	Castano 2012 (e.g. “Welcome to our study and thank u 4 participating”)
7. Set graded tasks	
8. Provide instruction	Castano 2012 (e.g. “Tell every doctor u see that u r taking the pill”; Hou 2010 (if “Please remember to take your birth control pill” is considered ‘telling a person how to perform a behaviour’); Smith 2014 (e.g. “press 1 if you would like me to call you back to discuss contraception”)
9. Model or demonstrate the behaviour	
10. Provide specific goal setting	
11. Prompt review of behavioural goals	
12. Prompt self monitoring of behaviour	Hou 2010 (women kept a diary of their daily pill taking; the intervention may have prompted this behaviour)
13. Provide feedback on performance	
14. Provide contingent rewards	
15. Teach or use	

prompts or cues	
16. Agree on behavioural contract	
17. Prompt practice	Hou 2010 ("Please remember to take your birth control pill"); Smith 2014 (participants who chose to receive the OC or injectable could receive additional reminders appropriate to their method); Trent 2013 (daily text appointment reminders 72 hours before the clinical visit)
18. Use follow-up prompts	
19. Provide opportunities for social comparison	
20. Plan social support or social change	Smith 2014 (If client received a phone call and requested, the counsellor would also discuss contraception with the husband or partner)
21. Prompt identification as a role model	
22. Prompt self-talk	
23. Relapse prevention	
24. Stress management	
25. Motivational interviewing	
26. Time management	

Outcomes

Primary outcomes were reported as follows: Three trials reported on adherence.

Castano 2012 defined OC continuation as the participant taking a pill within the previous seven days, assessed at six months.(142) Hou 2010 reported missed pills per cycle as measured by electronic monitoring device (EMD) over a three-month period.(143) Trent 2013 reported days between next scheduled appointment and attendance for Depo-Provera injection over three cycles (nine months).(171) Two trials reported contraception use. Smith 2014 assessed self-reported use of effective contraception, as assessed at four months (12 month follow-up is also planned).(170) Effective methods were considered as those with less than 10% failure rates as commonly used: OC, injectable, IUD, implant. Tsur 2008 assessed self-reported contraceptive use (methods not defined) at three months.(144)

Secondary outcomes were as follows: adherence (OC use at last sexual intercourse, interruptions in OC use greater than seven days, no missed pills during the past month) (Castano 2012), on-time appointment for Depo-Provera (Trent 2013), discontinuation of effective contraception (Smith 2014), long-acting⁵ contraception use (Smith 2014), contraception use over the follow-up period >80% (Smith 2014), condom use for at least 50% of coital activity during the study (Hou 2010), use of two contraceptives (Tsur 2008), sexually active and not using contraception (Tsur 2008), emergency contraception use (Hou 2010), pregnancy (Hou 2010; Smith 2014), repeat abortion (Smith 2014), unintended outcomes (road traffic accident, domestic abuse) (Smith 2014) and measures of satisfaction with the intervention (Castano 2012; Hou 2010).

Excluded studies

We excluded three studies when mobile phones were used for two-way voice communication (as a phone) alone;(172)(173)(174) two studies when the intervention was web-based or tablet-based and did not appear to have been adapted for mobile phone users;(175)(176) three studies that did not have relevant outcome measures;(177)(178)(179) five studies in which the intervention focused on preventing sexually transmitted disease rather than on providing contraception;(180)(181)(182)(183)(184) and four studies that were not randomised controlled trials.(146)(185)(186)(187) We provided details in Table 6.

⁵ Intrauterine device, implant or permanent method

Table 6: Characteristics of excluded studies

Study	Reason for exclusion
Bannink 2014	Web-based intervention that does not appear to have been intended or adapted for mobile phone users
Berenson 2012	Phone call only intervention
Bracken 2014	No relevant contraception outcome measure
Constant 2014	Post-abortion family planning not the main focus of the intervention and not reported
Gold 2011	Focus on preventing sexually transmitted disease rather than on providing contraception
Hall 2013	Additional analysis of Castano 2012 but no relevant outcome measure (reported contraceptive knowledge)
Juzang 2011	Focus on preventing sexually transmitted disease rather than on providing contraception
Kaoaiem 2012	Focus on preventing sexually transmitted disease rather than on providing contraception, 'quasi-experimental' design
Katz 2011	Phone call only intervention
Kirby 2010	Phone call only intervention
L'Engle 2013	Not a randomised controlled trial
Lim 2012	Focus on preventing sexually transmitted disease rather than on providing contraception
Mackenzie 2009	Not a randomised controlled trial
O'Sullivan 2008	Not a randomised controlled trial
Sridhar 2013	Tablet-based application for contraceptive counselling not adapted for mobile phone users
Suffoletto 2013	Focus on preventing sexually transmitted disease rather than on providing contraception
Walakira 2013	Not a randomised controlled trial (longitudinal comparison study)

Risk of bias in included studies

We summarised risk of bias in Figure 6 and Figure 7. For Trent 2013,(171) the conference abstract provided insufficient information for full assessment of risk of bias, but we were able to obtain additional data from the study investigator.

Figure 6: Risk of bias summary: review authors' judgements about each risk of bias item for each included study

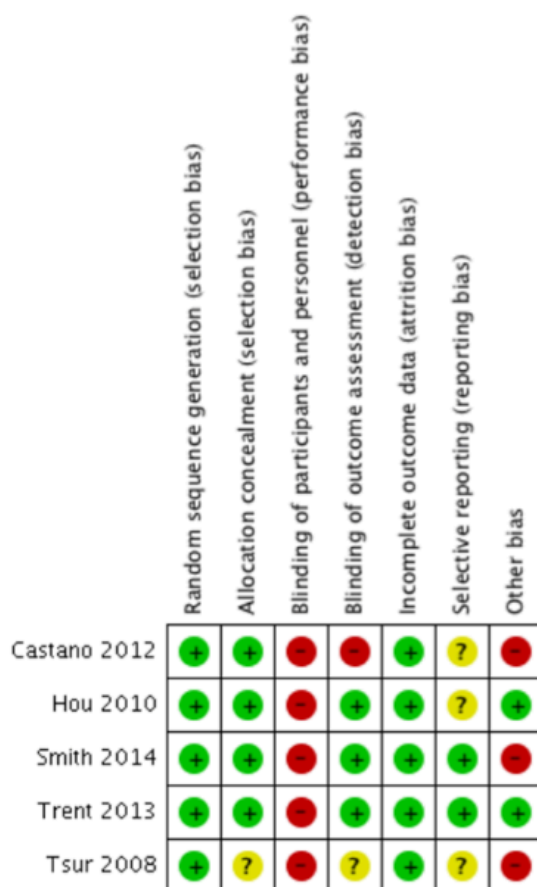
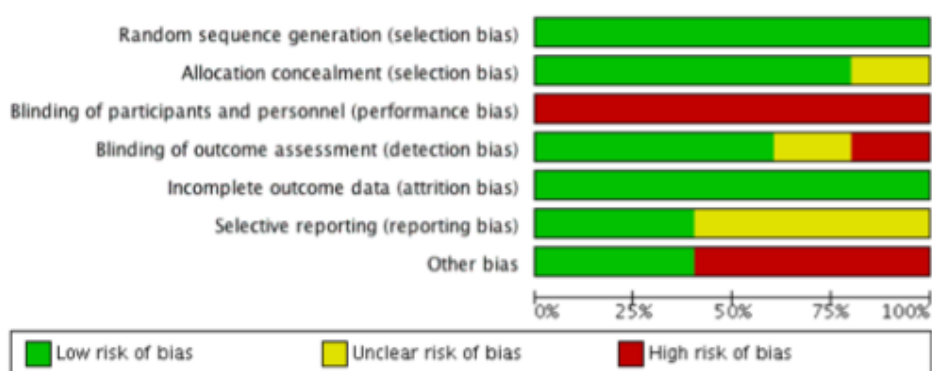


Figure 7: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Allocation

All five studies specified random sequence generation methods. Four studies used computer-generated sequences (Hou 2010; Smith 2014; Trent 2013; Tsur 2008), and

one study used a random number table (Castano 2012). Four studies specified adequate allocation concealment methods (Castano 2012; Hou 2010; Smith 2014; Trent 2013), and in the remaining study these methods were unclear (Tsur 2008).

Blinding

As a result of the nature of the interventions, it was not possible to blind participants to intervention allocation; therefore the outcome could have been influenced by lack of blinding, resulting in performance bias. Hou 2010 reported that 68% of participants in the control group used a reminding system outside of the study protocol (e.g. alarm clock, mobile phone alarm) compared with 36% in the intervention group (P value = 0.003). This could have occurred in response to participation in the trial or frequent use of reminding systems in general.

Three studies reported outcome assessment as blinded (Hou 2010; Smith 2014; Trent 2013), but this was not stated in two studies (Castano 2012; Tsur 2008). In Castano 2012 and Hou 2010, participants were asked questions regarding their satisfaction with the intervention.

Incomplete outcome data

One trial reported loss to follow-up of 20% or more (Castano 2012): 28% in the intervention group and 30% in the control group.

Selective reporting

One trial (Smith 2014) pre-specified primary and secondary outcomes in its study protocol (Smith 2013). Three trials provided information on outcomes on a clinical trials registry (Castano 2012; Hou 2010; Trent 2013). For one trial, we were unable to locate a study protocol or a clinical trials registry record (Tsur 2008).

Other potential sources of bias

Two trials used objective measures for the primary outcome (Hou 2010; Trent 2013).

Hou 2010 assessed mean pills missed per cycle using an electronic medication monitor, in addition to a self-report patient diary. The overall rate of missed pills was 4.7 ± 3.2 per cycle according to the electronic monitoring device, and 1.2 ± 1.5 per cycle according to the patient diary (P value <0.001). Trent 2013 assessed attendance for Depo-Provera appointments using clinic records.

Three studies used self-report measures for the primary outcome (Castano 2012; Smith 2014; Tsur 2008). Castano 2012 defined adherence as participants reporting that they took OC within the previous seven days. Smith 2014 defined self reported contraception use according to one of these methods: Participants currently had an implant or an IUD inserted; participants had received an injection within the previous three months; participants or husbands or partners had undergone a sterilisation or vasectomy procedure; or participants reported that they had taken OC within 24 hours of the interview or according to instructions. In addition, Smith 2014 attempted to conduct objective measurements amongst 50 participants to validate self-report measures. Tsur 2008 did not report how contraceptive use was assessed.

Effects of interventions

See Table 7.

Table 7: Summary of findings for the main comparison

Intervention delivered by mobile phone compared with standard care to improve contraception use				
Patient or population: female users or non-users of contraception Settings: Various: USA, Cambodia, Israel Intervention: text messaging, voice messaging, telephone counselling Comparison: standard care (clinic-based counselling), no additional mobile phone-based support				
Outcomes	Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Intervention
OC use (continuation) at 6 months	RR 1.19 (1.05 to 1.35)	683 (Castano 2012)	⊕⊕○○ Low	Intervention comprised a range of different daily educational text messages for 180 days
Effective contraception use at 4 months	RR 1.39 (1.17 to 1.66)	431 (Smith 2014)	⊕⊕⊕⊕ High	Intervention comprised a series of six voice messages ± counsellor delivered support
Mean number of missed pills (cycle 1)	Mean difference 0.5 missed pills (-1.08 to 2.08)	73 (Hou 2010)	⊕⊕⊕○ Moderate	Intervention comprised daily contraceptive pill reminder text message for 3 months
Contraceptive use during treatment with Isotretinoin at 3 months	RR 1.26 (0.84 to 1.89)	108 (Tsur 2008)	⊕○○○ Very low	Intervention comprised 2 text messages together with information via mail
Mean number of days between scheduled appointment and completed visit for Depo-Provera: first visit	Mean difference -8.60 days (-16.74 to -0.46)	87 (Trent 2013)	⊕⊕⊕○ Moderate	Intervention comprised daily text message appointment reminders 72 hours before appointment and healthy self management messages
GRADE Working Group grades of evidence. High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.				

Primary outcomes

Three trials assessed adherence to a specific method of contraception. In Castano 2012, participants receiving daily educational text messages were more likely to report OC continuation at six months (RR 1.19, 95% CI 1.05 to 1.35) (Figure 8). In Hou 2010, no significant difference was noted in the mean number of missed pills per contraceptive pill cycle using the electronic monitoring device between the text message group and the control group during cycle one (MD 0.5 missed pills, 95% CI -1.08 to 2.08) (Figure 9), cycle two or cycle three (MD 0.80 missed pills; 95% CI -1.22 to 2.82) (Figure 10). Trent 2013 reported that the group receiving text message

reminders and healthy self management messages had a lower mean number of days between scheduled appointment and actual attendance for Depo-Provera injection for visit one (MD -8.60 days, 95% CI -16.74 to -0.46) (Figure 11) but not for visit two or three (Figure 12) (data obtained from study investigator). Two trials assessed uptake and adherence to more than one method of contraception. In Smith 2014, participants receiving voice messages and counsellor support were more likely to report using effective contraception at four months post abortion (RR 1.39, 95% CI 1.17 to 1.66) (Figure 13). In Tsur 2008, no significant difference in contraceptive use was observed between participants receiving text messages together with information received via mail and the control group (RR 1.26, 95% CI 0.84 to 1.89) (Figure 14).

Figure 8: Comparison 1 Daily educational text messages vs. no messages, Outcome 1 OC use (continuation) at 6 months

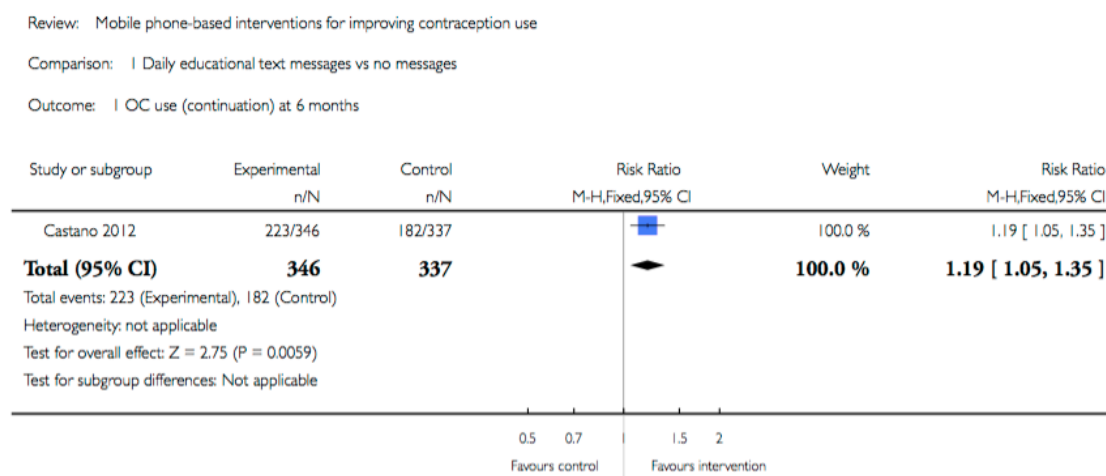


Figure 9: Comparison 2 Daily text message reminders vs. no reminders, Outcome 1 Mean number of missed pills (cycle 1)

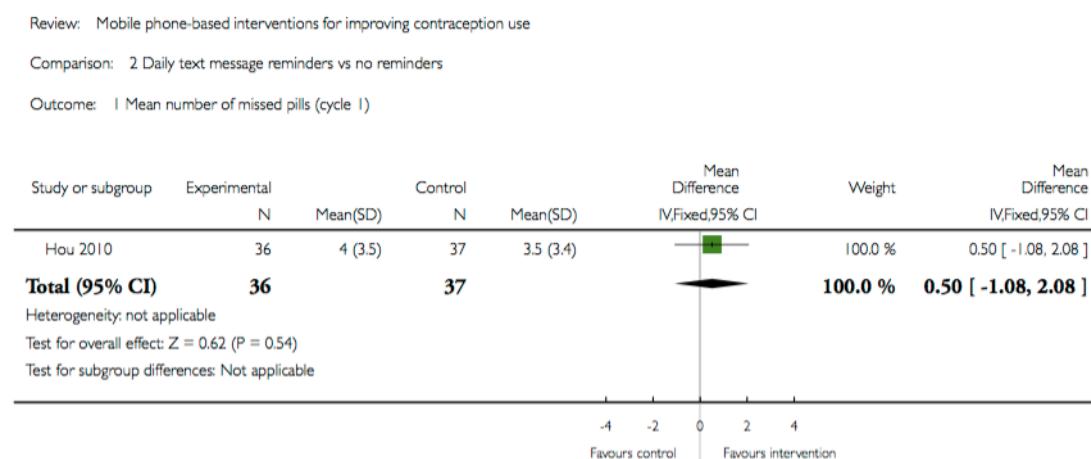


Figure 10: Comparison 2 Daily text message reminders vs. no reminders, Outcome 2 Mean number of missed pills (cycle 3)

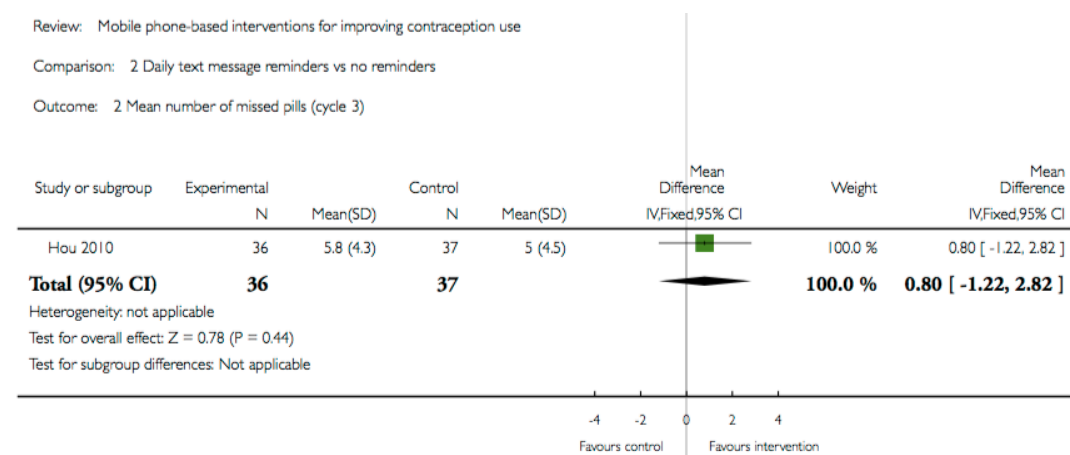


Figure 11: Daily text message appointment reminders vs. standard care, Outcome 1 Mean number of days between scheduled appointment and completed visit: first visit

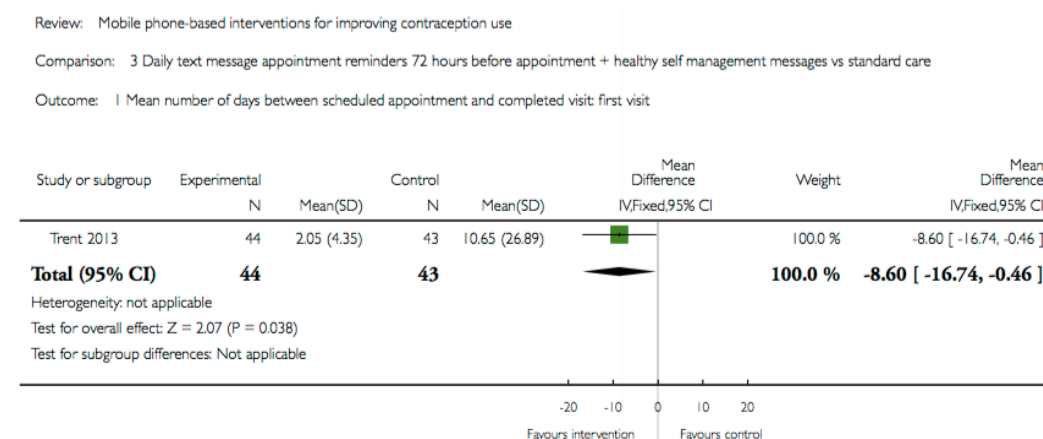


Figure 12: Daily text message appointment reminders vs. standard care, Outcome 2 Mean number of days between scheduled appointment and completed visit: third visit

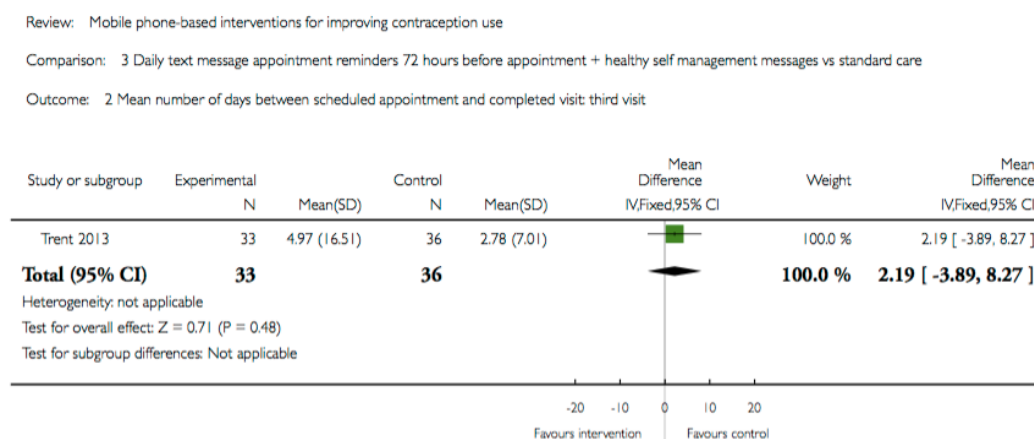


Figure 13: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 1 Effective contraception use at 4 months

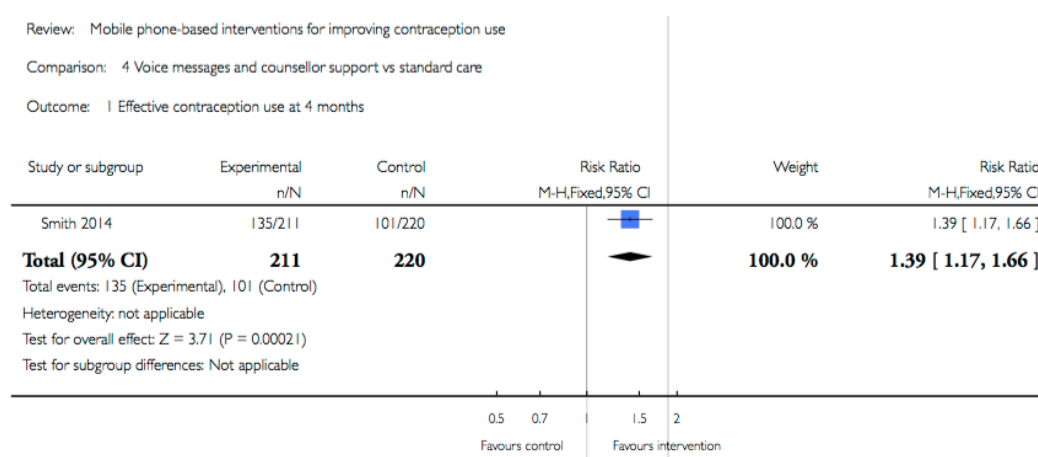
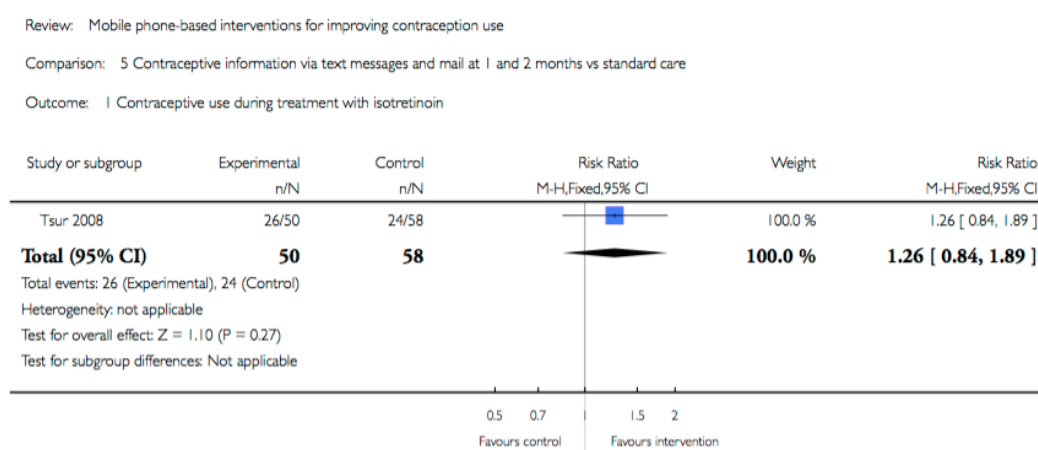


Figure 14: Comparison 5 Contraceptive information via text messages and mail vs. standard care, Outcome 1 Contraceptive use during treatment with isotretinoin



Secondary outcomes

Four trials assessed measures of adherence. In Castano 2012, participants receiving

the intervention were more likely to report no OC interruptions longer than seven days at six months (RR 1.22, 95% CI 1.06 to 1.41) (Figure 15), more likely to report that they had missed no pills in the previous month (RR 1.44, 95% CI 1.16 to 1.79) (Figure 16) and more likely to report OC use at last sexual intercourse (RR 1.15, 95% CI 1.03 to 1.28) (Figure 17). In Hou 2010, participants receiving the intervention were more likely to report condom use for at least 50% of coital activity during the study (RR 1.94, 95% CI 1.00 to 3.78) (Figure 18). In Smith 2014, participants receiving the intervention were more likely to use contraception over the four-month post-abortion period (> 80%, RR 1.35, 95% CI 1.10 to 1.67) (Figure 19) and less likely to discontinue effective contraception if they had started a method during the first four weeks post abortion (hazard ratio 0.45, 95% CI 0.20 to 1.01). For Trent 2013, the abstract reported no overall differences among those who received injections within the optimal Depo-Provera window due to additional clinical nursing outreach that resulted from missed visits per the existing clinical protocol for standard care.

Figure 15: Comparison 1 Daily educational text messages vs. no messages, Outcome 4 No OC interruptions >7 days at 6 months

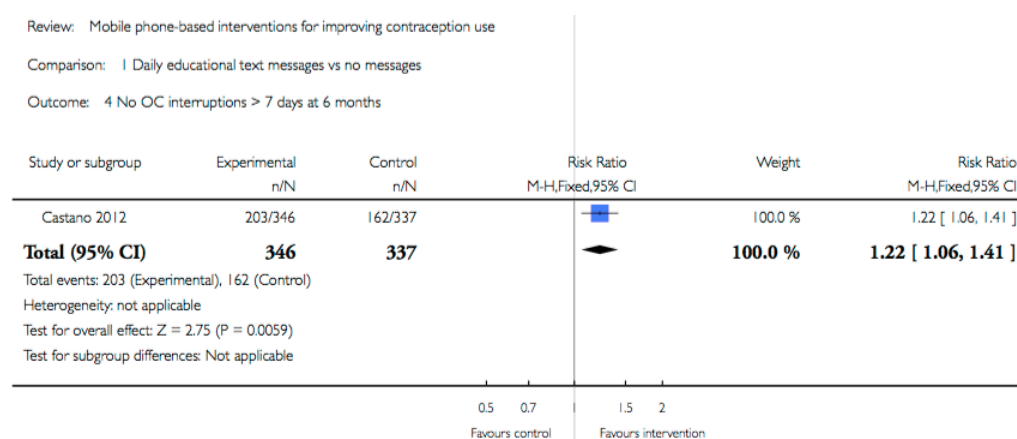


Figure 16: Comparison 1 Daily educational text messages vs. no messages, Outcome 5 Missed no pills in last month

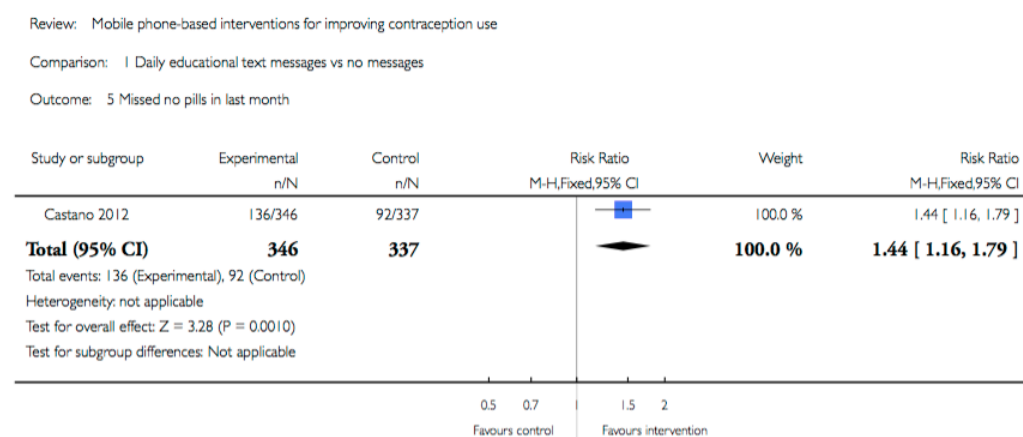


Figure 17: Comparison 1 Daily educational text messages vs. no messages, Outcome 6 OC use at last intercourse

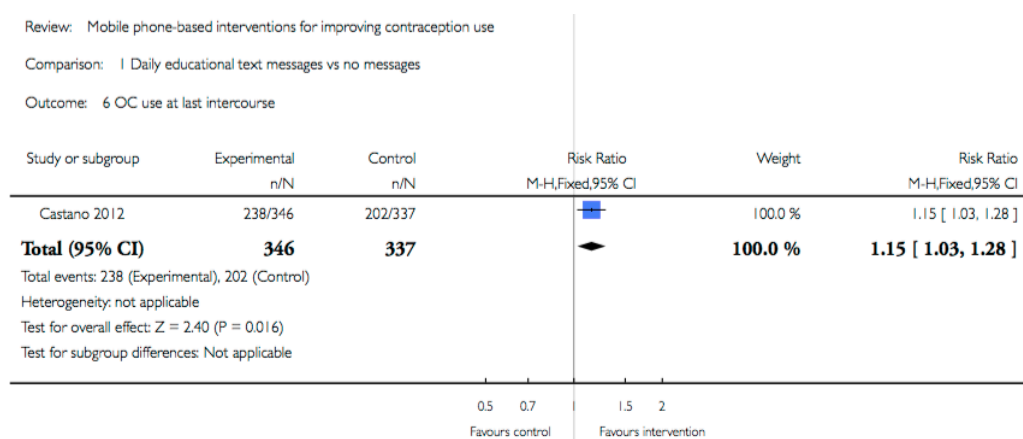


Figure 18: Comparison 2 Daily text message reminders vs. no reminders, Outcome 3 Condom use for at least 50% of coital activity during the study

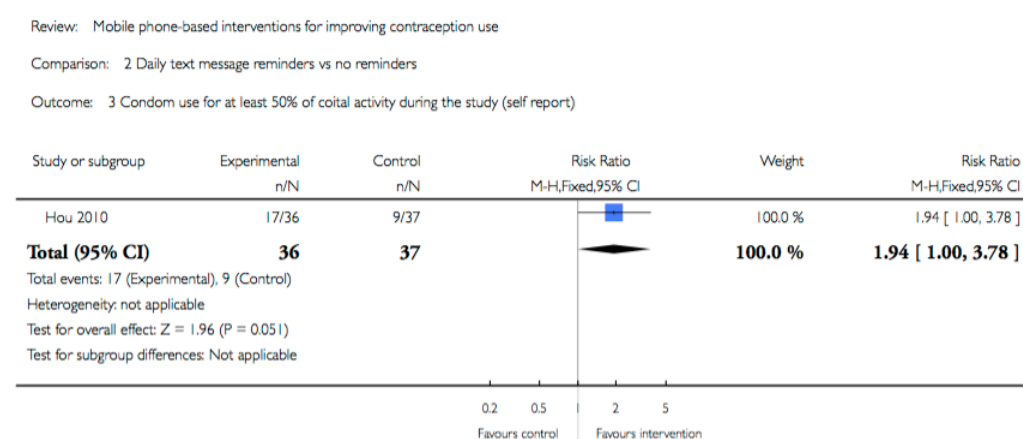
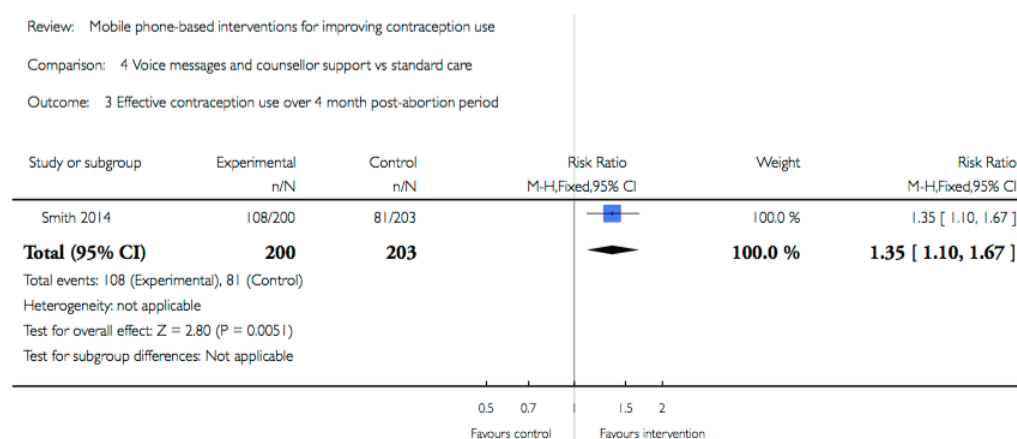


Figure 19: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 3 Effective contraception use over 4 month post-abortion period



Three trials assessed use of additional contraceptive methods. In Smith 2014, participants receiving the intervention were more likely to be using long-acting contraception (IUD, implant, or permanent method) at four months (RR 3.35, 95% CI 2.07 to 5.40) (Figure 20). In Hou 2010, no difference was noted between intervention and control groups regarding emergency contraception use, but few events were reported (Figure 21). In Tsur 2008, no difference was observed between intervention and control groups regarding using two contraceptives or being sexually active and not using contraception at three months, but few events were reported (Figure 22; Figure 23).

Figure 20: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 2 Long-acting contraception use at 4 months

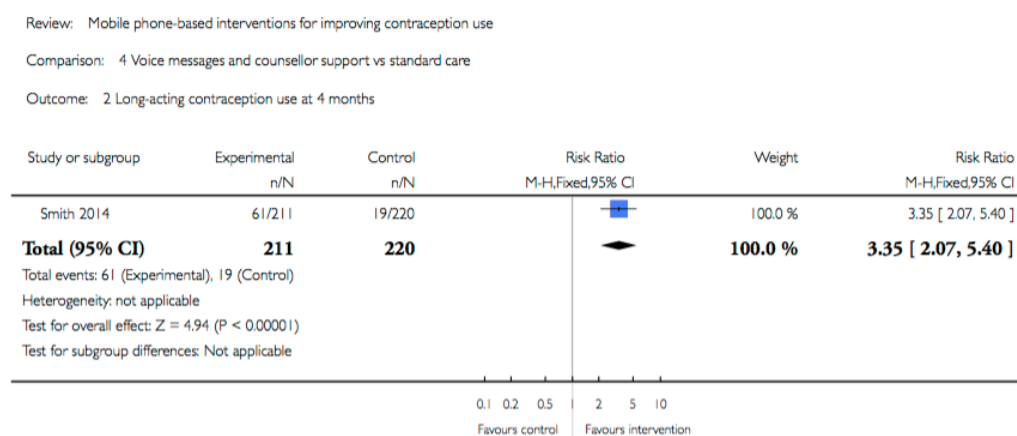


Figure 21 Comparison 2 Daily text message reminders vs. no reminders, Outcome 4 Emergency contraception use during the study

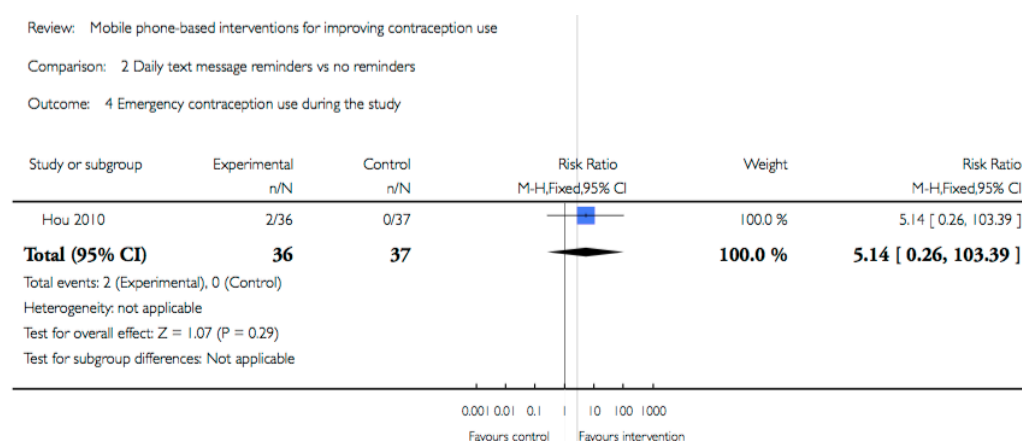


Figure 22: Comparison 5 Contraceptive information via text messages and mail vs. standard care, Outcome 2 Use of 2 contraceptives

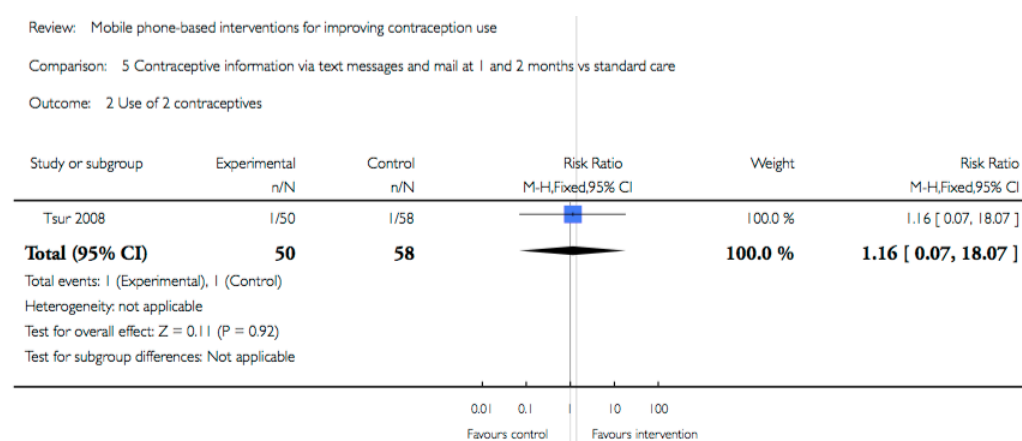
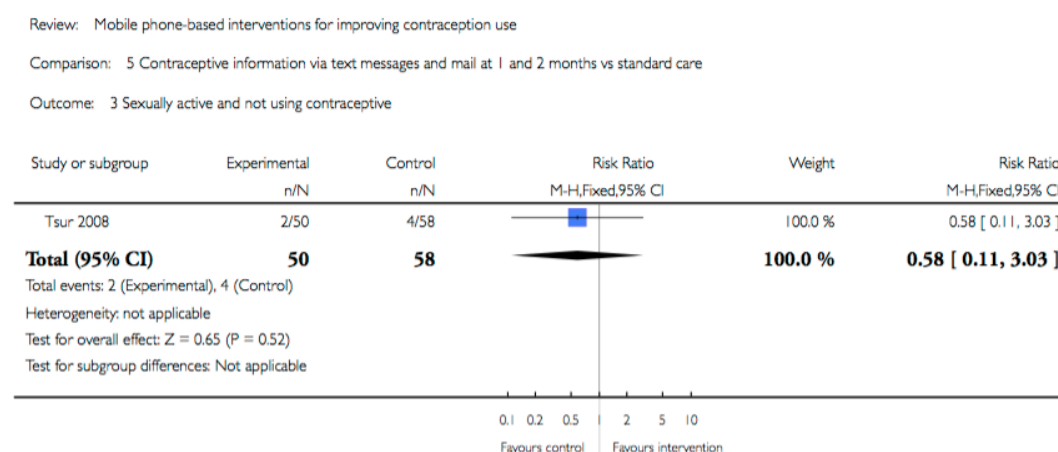


Figure 23: Comparison 5 Contraceptive information via text messages and mail vs. standard care, Outcome 3 Sexually active and not using contraceptive



Two trials assessed pregnancy, and one trial assessed repeat abortion. In Hou 2010, no

pregnancies were reported during the trial period. In Smith 2014, no difference was noted between intervention and control groups in repeat pregnancy or abortion at four months, but few events were reported (Figure 24; Figure 25). One trial assessed potential unintended outcomes. In Smith 2014, no road traffic accidents or domestic abuse was reported (Figure 26; Figure 27).

Figure 24: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 4 Repeat pregnancy at 4 months

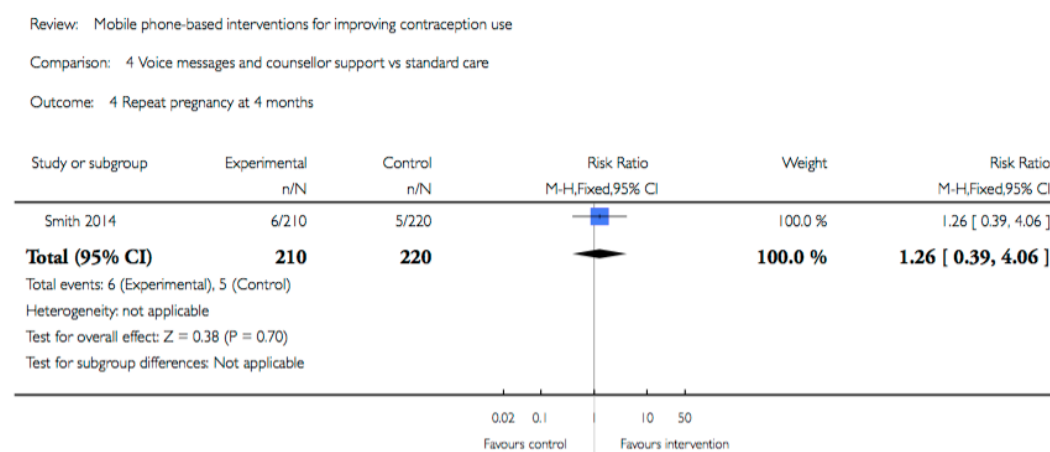


Figure 25: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 5 Repeat abortion at 4 months

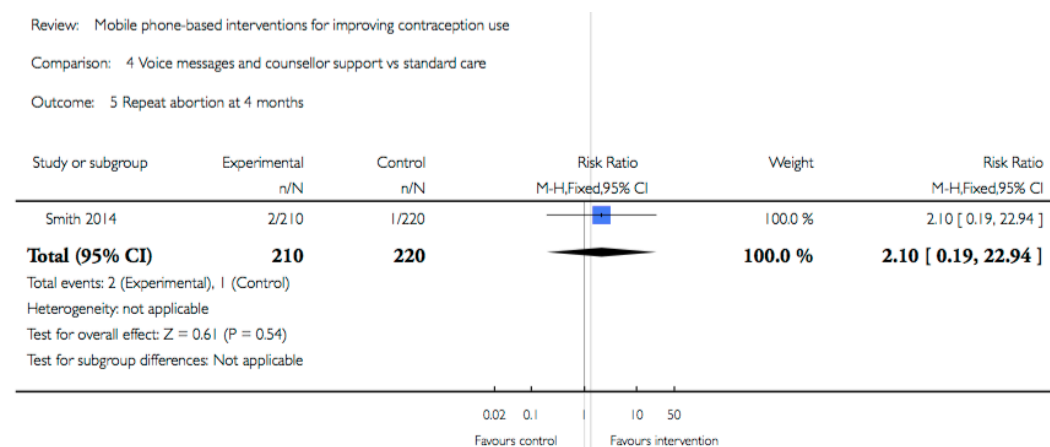


Figure 26: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 6 Road traffic accident

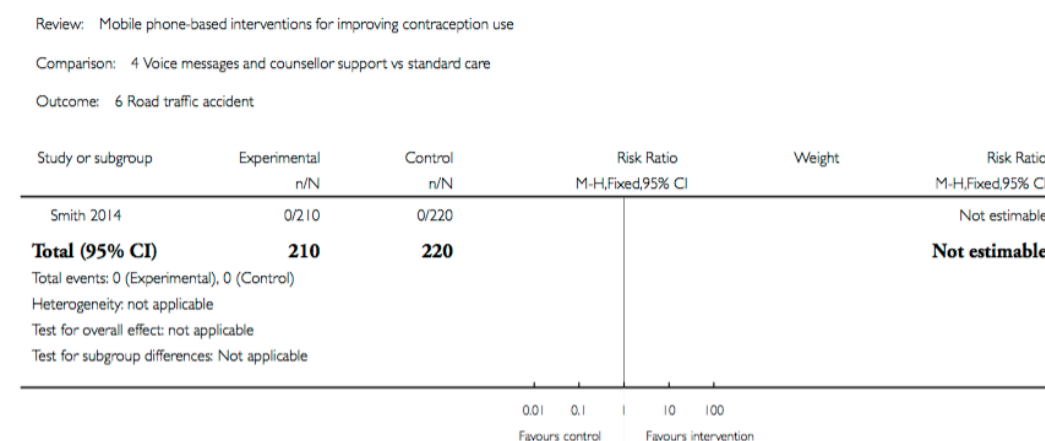
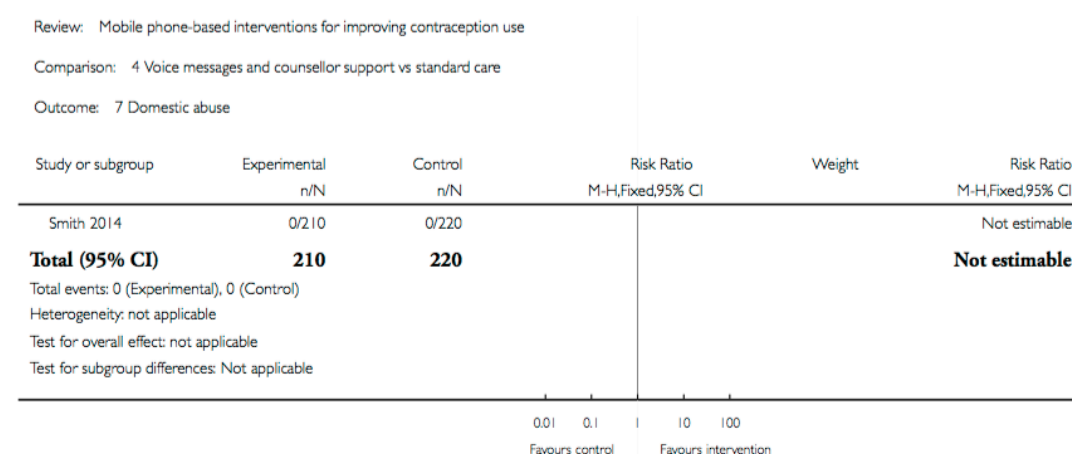


Figure 27: Comparison 4 Voice messages and counsellor support vs. standard care, Outcome 7 Domestic abuse



Exploratory analyses

Castano 2012 undertook an exploratory analysis to assess whether the effect of the intervention on the primary outcome differed if follow-up occurred whilst the participant was still receiving the intervention. Participants receiving the intervention were more likely to report OC continuation if follow-up took place whilst the intervention was on-going (RR 1.41, 95% CI 1.13 to 1.74) (Figure 28), and no evidence of effect was found if follow-up was provided after the intervention ended (RR 1.11, 95% CI 0.95 to 1.29) (Figure 29).

Figure 28: Comparison 1 Daily educational text messages vs. no messages, Outcome 2 OC use (continuation): follow up 187 days or less

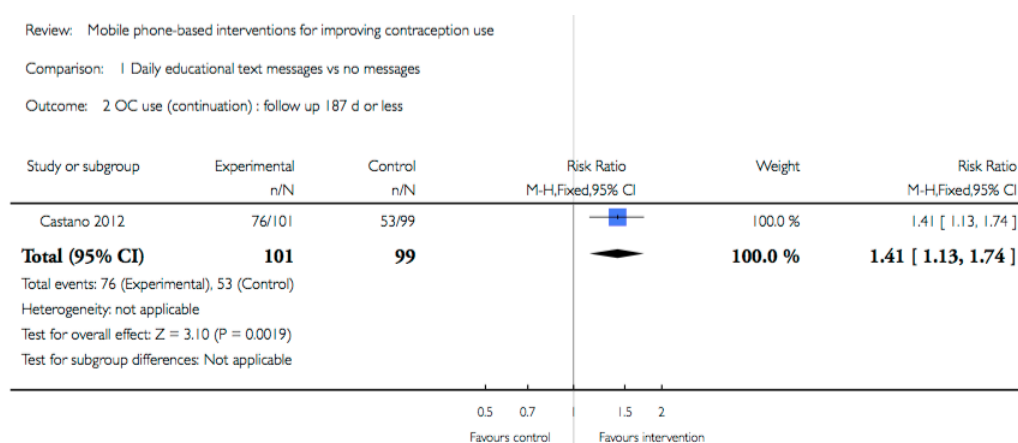
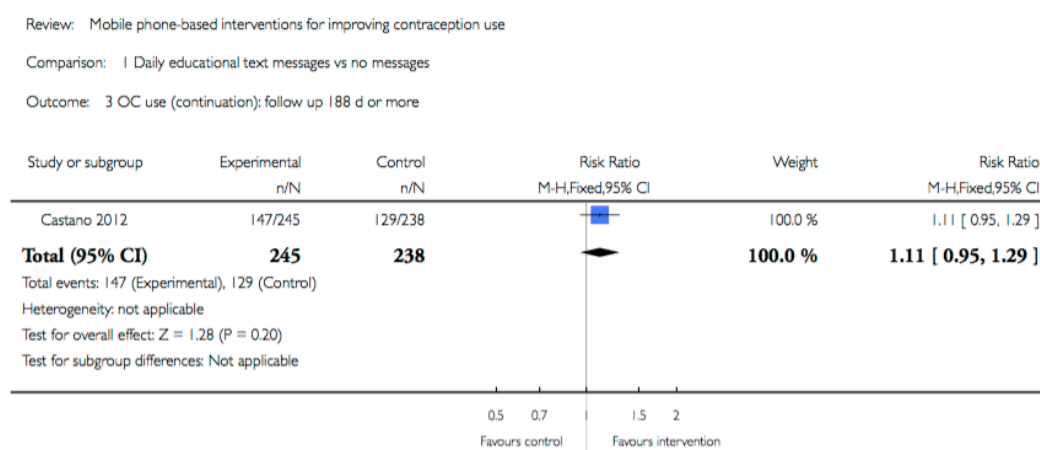


Figure 29: Comparison 1 Daily educational text messages vs. no messages, Outcome 3 OC use (continuation): follow up 188 days or more



2.6 Discussion

Summary of main results

Our review provides limited evidence that interventions delivered by mobile phone improve contraception use. We identified five trials - three assessing adherence to a specific method of contraception and two assessing both uptake and adherence to more than one method. Most trials were conducted in high-income countries. Differences in interventions and outcomes measures did not permit us to undertake meta-analysis.

Two trials reported increased self reported contraception use. One trial in the USA

reported improved OC continuation from an intervention comprising a range of uni-directional and interactive text messages amongst participants who were still receiving the intervention (Castano 2012).(142) One trial in Cambodia reported increased use of effective contraception at four months post abortion from an intervention comprising automated interactive voice messages and phone counsellor support (Smith 2014).(170) One feasibility trial in the USA reported a lower mean number of days between scheduled and completed attendance for the first but not subsequent Depo-Provera appointments using clinic records from an intervention comprising reminders and healthy self management text messages (Trent 2013).(171) Simple text messages as OC reminders had no effect on missed pills assessed by electronic medication monitor in a small trial in the USA (Hou 2010).(143) No effect on self reported contraception use was observed amongst isotretinoin users from an intervention that provided health information via two uni-directional text messages and mail (Tsur 2008).(144) Only one trial assessed potential adverse effects of the intervention and reported no evidence of road traffic accidents or domestic abuse (Smith 2014).(170)

Overall completeness and applicability of evidence

As predicted on the basis of previous reviews of mobile phone-based interventions,(123)(124) we identified insufficient high-quality studies to address the objectives of the review, and thus its external validity. Evidence is insufficient to recommend a particular mode or frequency of communication. We cannot draw conclusions on the effectiveness of interventions delivered by mobile phone among younger or older populations, in high- or low-income settings or among different outcomes, whether they involve uptake of or adherence with contraception. However, we identified several on-going studies that may be included in future updates of this

review.

At present, interventions delivered by mobile phone to increase contraception use are not standard practice for contraceptive service delivery organisations. Our review findings suggest that additional mobile phone-based interventions to increase contraception use could be used in two contexts. First, daily educational text message reminders can improve self-reported OC adherence in young females at the time they are receiving the intervention. Second, interactive voice messages and counsellor support can increase self-reported use of effective contraception at four months post abortion. However, the follow caveats should be considered. First, information on the cost-effectiveness of these interventions is lacking at the present time. None of the included studies presented data on intervention costs, although we may have identified articles if we had explicitly searched for cost-effectiveness analyses. Second, the duration of follow-up in all of the included trials ranged between three months and 12 months, and the long-term effect of these interventions is unclear. Third, it is likely that these interventions would require adaptation for different settings, and it is not clear what behaviour change techniques, or combinations of, are effective. Lack of theory in the interventions was a limitation of all included studies. We used Abraham and Michie's typology of behaviour change techniques to code intervention content according to the intervention description provided in the papers or in protocols, which varied in the level of detail provided. Three trials provided details of specific message content (Castano 2012; Hou 2010; Smith 2014).(142)(143)(170) Coding of the intervention content could have been more complete and accurate if additional detail on messages and other intervention content had been provided. The effective interventions used four (Castano 2012) or five (Smith 2014) behaviour change

techniques, whilst the interventions that were not reported to be effective used two (Trent 2013; Tsur 2008) or three (Hou 2010) behaviour change techniques (Table 5).(142)(143)(170)(144)(171) An inadequate number of studies assessed associations between use of particular behaviour change techniques and effectiveness of interventions.

Our review excluded studies in which mobile phones were used for two-way voice communication alone. However, some of the excluded studies were recent and utilised mobile phones; therefore future reviews should consider inclusion of such studies. Our review did not include studies that aimed to increase contraceptive knowledge alone. Interventions that increase knowledge of contraception may lead to increased uptake and adherence, and future reviews should consider inclusion of such studies.

Quality of the evidence

We summarised the quality of evidence in Table 8 using the GRADE approach. We downgraded two trials because of limitations in design and implementation; lack of or insufficient information on blinding (Castano 2012; Tsur 2008); or large losses to follow-up (Castano 2012).(142)(144)

We downgraded one trial for indirectness of evidence, as it addressed a restricted version of the main review question by including only participants using a medication for acne, which could affect the generalisability of this study to other populations (Tsur 2008).(144) We downgraded three trials with small sample sizes for imprecision of results (Hou 2010; Trent 2013; Tsur 2008).(143)(171)(144) Overall, evidence was of high quality for one trial, moderate for two trials, low for one trial and very low for one trial.

Table 8: Results by quality of evidence

Study	Limitations in design and implementation	Indirectness of evidence	Unexplained heterogeneity or inconsistency of results	Imprecision of results	High probability of publication bias	Quality of evidence	Evidence of effect
Castano 2012	-2					Low	Yes
Hou 2010				-1		Moderate	No
Smith 2014						High	Yes
Trent 2013				-1		Moderate	Yes
Tsur 2008	-1	-1		-1		Very low	No

Randomised controlled trials were considered of high quality, then were downgraded by one level (serious) or two levels (very serious) for each of the following: limitations in design and implementation (e.g. lack of blinding, large losses to follow-up), indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results, high probability of publication bias.

No trials were at low risk of bias in all areas assessed. Performance bias may have arisen from altered behaviour of participants based on allocation to the intervention or control group. Detection bias may have arisen as the result of lack of outcome assessment blinding, which was not apparent in all of the trials. Furthermore, bias may have arisen from use of self-report measures of contraception. Although the standard in contraceptive research, self report measures have been shown to overestimate contraceptive use and underestimate abortion.(188) Hou 2010 reported increased poorer OC adherence as measured by electronic medication monitoring compared with the patient diary.(143) However, it should be considered that no gold standard measure of OC use is available, and objective assessment is challenging, as biological measures such as hormonal assays do not indicate consistent use.(189) To date, electronic medication monitors have been costly, and the appearance of the devices themselves could interfere with the intervention.

Participants randomly assigned to the intervention may have shared intervention content with participants recruited from the same centre, resulting in contamination

across study groups and weakening of overall effect. None of the included trials reported on this. Three trials, all of which found no effect, included small sample sizes, which increased the possibility of Type II error (Hou 2010; Trent 2013; Tsur 2008).(143)(171)(144)

Agreements and disagreements with other studies or reviews

To our knowledge, this is the first systematic review of mobile phone-based interventions to improve contraception use. Our observation that interventions found to increase contraception use were multi-faceted and more intensive is consistent with evidence on strategies to improve adherence and acceptability of hormonal methods of contraception.(92) The finding that simple text message reminders had no effect is consistent with existing mHealth evidence from systematic reviews and trials that simple text message reminders have at best small effects (pooled RR 1.0, 95% CI 0.77 to 1.30), as well as findings of face-to-face adherence research.(134)(115)(133)

Complex interventions delivered by mobile phone have been shown to be effective in other conditions, including human immunodeficiency virus (HIV) medication adherence and smoking cessation.(115)(123)(127)(132)(125) Interventions for different conditions should be compared with caution, as it is likely that factors influencing contraception use will be different from those influencing adherence to antiretroviral therapy or smoking cessation. However, mobile phone-based interventions for HIV medication adherence are similar to those for contraception in the respect that they include populations for which confidentiality and privacy are of particular importance, and they can involve similar behaviours (i.e. taking a tablet). A Cochrane review of mobile phone text messaging for promoting adherence to antiretroviral therapy reported good evidence that text message support can improve

adherence to treatment compared with standard care (Horvath 2012).(123) However, since that time, Shet 2014 has reported no effect on virologic failure at two years when medication reminders were delivered by mobile.(133) Thus, evidence for mobile phone-based interventions for HIV adherence to date, as for contraception, is mixed and is likely to be dependent on intervention content, as well as the mechanism of delivery (mobile phone). Shared learning between researchers in different fields may occur over time.

2.7 Authors' conclusions

Implications for practice

At the present time, evidence is insufficient to support widespread implementation of mobile phone-based interventions to increase contraception use. Whilst evidence indicates that a series of interactive voice messages and counsellor support can improve post-abortion contraception, and that a mixture of uni-directional and interactive daily educational text messages may improve OC adherence, the cost-effectiveness and long-term effects of these interventions remain unknown.

Interventions delivered by mobile phone should be considered as part of the wider health service delivery. Future mobile phone-based interventions should consider the context and needs of the population, for example, literacy, phone use, use of other services and what behaviour change techniques delivered by mobile phone are likely to be effective.

Implications for research

Further high-quality trials are required to robustly establish the effects of interventions delivered by mobile phone to increase contraception use. Larger trials could be powered for pregnancy and abortion outcomes. Trials should be complemented by

process evaluations to enhance understanding of the mechanism that explains why a certain intervention works or does not work. The cost-effectiveness of effective interventions should be established. To build the evidence base regarding which interventions and intervention components are effective, future interventions should be described in detail together with conceptual frameworks and use of theory, as appropriate. This would enable assessment of behaviour change techniques and replication or modification of interventions elsewhere. In areas where interventions have yielded inconclusive evidence, such as fully automated text message interventions for OC adherence, future research should focus on improving interventions before considering future evaluation by randomised controlled trials. Interventions that aim to improve adherence to a single method should consider additional facilitation of safe method switching, given that side effects and health concerns leading to discontinuation are common.

Consideration should be given to choice of outcome measures, whether measures of uptake or adherence. Use of consistent outcome measures would allow pooling of results and meta-analysis in future reviews. Trials should aim to objectively assess contraception use, if feasible. If self-report measures are used, outcome assessment should be blinded and questions carefully considered to reduce the likelihood of courtesy bias. For long-acting contraception, objective measures of use such as clinical examination to assess IUD position are likely to be more robust but may be costly and less acceptable to patients, resulting in increased attrition. If appropriate, data on contraception use such as injectable methods could be obtained from clinical records. To assess oral contraceptive use, electronic medication monitors that have the same appearance as contraceptive pill blister packs should be considered.

Table 9: Cochrane review search strategies

MEDLINE via Ovid (date of search: 6 October 2014)

(phone adj3 call*).mp. OR ((cell* or mobile or smart or Google or nexus or iPhone) adj3 (phone* or telephone*)).mp. OR smart- phone*.mp. OR smart-phone*.mp. OR (blackberr* not extract).mp. OR (black-berr* not extract).mp. OR ((mobile adj3 health) not (van* or unit*)).mp. OR mhealth.mp OR m-health.mp OR e-health*.mp. OR eHealth*.mp. OR (electronic adj health).mp. OR (mobile adj3 technol*).mp. OR ((mobile or smartphone or smart-phone or phone or software) adj3 app*).mp. OR MMS.mp. OR multimedia messaging service.mp OR SMS.mp. OR short messag* service.mp OR (text* adj messag*).mp. OR text-messa*.mp. OR voice messag*.mp. OR interactive voice response.mp OR IVR.mp. OR Telemedicine/ OR cellular phone/ or text messaging/

AND (contracept* or (family adj planning) or (Birth adj control)).mp. OR condom.mp. OR (OC adj pill).mp. OR (depot medroxyprogest* or NET-EN or NET EN or Mesigyna or Cyclofem).mp. OR (intrauterine system or intra-uterine system or IUS or intrauterine device or intra-uterine device or IUD).mp. OR (vasectomy or sterilisation or sterilization or (tubal adj ligation)).mp. OR ((vaginal adj ring) or cycletel or cycle-tel or abstain or abstinen* or lactational amenorr*).mp OR (pregnan* or abortion).mp OR exp Contraception/ OR exp Contraceptive Devices/ OR exp Pregnancy, Unplanned/ OR exp Pregnancy, Unwanted/ OR exp Abortion, Induced/ OR (NORPLANT or implanon or Femplant).mp. Limit to yr="1993-Current" and clinical trial, all

Global Health via Ovid (date of search: 6 October 2014)

(phone adj3 call*).mp. OR ((cell* or mobile or smart or Google or nexus or iPhone) adj3 (phone* or telephone*)).mp. OR smart- phone*.mp. OR smart-phone*.mp. OR (blackberr* not extract).mp OR (black-berr* not extract).mp OR ((mobile adj3 health) not (van* or unit*)).mp. OR mhealth.mp OR m-health.mp. OR e-health*.mp. OR ehealth*.mp OR (electronic adj health).mp OR (mobile adj3 technol*).mp OR ((mobile or smartphone or smart-phone or phone or software) adj3 app*).mp. OR MMS.mp OR multimedia messaging service.mp OR SMS.mp. OR short messag* service.mp OR (text* adj messag*).mp. OR text-messa*.mp. OR voice messag*.mp. OR interactive voice response.mp OR IVR.mp OR Telemedicine/ OR cellular phone/ or text messaging/ OR exp mobile telephones/ AND (contracept* or (family adj planning) or (Birth adj control)).mp. OR condom.mp OR (OC adj pill).mp. OR (depot medroxyprogest* or NET-EN or NET EN or Mesigyna or Cyclofem).mp. OR (intrauterine system or intra-uterine system or IUS or intrauterine device or intra-uterine device or IUD).mp. OR (vasectomy or sterilisation or sterilization or (tubal adj ligation)).mp. OR ((vaginal adj ring) or cycletel or cycle-tel or abstain or abstinen* or lactational amenorr*).mp OR (pregnan* or abortion).mp OR exp Contraception/ OR exp Contraceptive Devices/ OR exp Pregnancy, Unplanned/ OR exp Pregnancy, Unwanted/ OR exp Abortion, Induced/ OR (NORPLANT or implanon or Femplant).mp. OR induced abortion/

Limit to yr="1993-Current"

PsycINFO via Ovid (date of search: 6 October 2014)

(phone adj3 call*).mp. OR ((cell* or mobile or smart or Google or nexus or iPhone) adj3 (phone* or telephone*)).mp. OR smart- phone*.mp OR smart-phone*.mp. OR (blackberr* not extract).mp OR (black-berr* not extract).mp OR ((mobile adj3 health) not (van* or unit*)).mp OR mhealth.mp. OR m-health.mp. OR e-health*.mp. OR ehealth*.mp OR (electronic adj health). OR (mobile adj3 technol*).mp OR ((mobile or smartphone or smart-phone or phone or software) adj3 app*).mp. OR MMS.mp. OR multimedia messaging OR SMS.mp. OR short messag* service.mp OR (text* adj messag*).mp OR text-messa*.mp OR voice messag*.mp OR interactive voice response.mp OR IVR.mp OR Telemedicine/ OR cellular phone/ or text messaging/

AND (contracept* or (family adj planning) or (Birth adj control)).mp OR condom.mp. OR (OC adj pill).mp OR (depot medroxyprogest* or NET-EN or NET EN or Mesigyna or Cyclofem).mp OR (intrauterine system or intra-uterine system or IUS or intrauterine device or intra-uterine device or IUD).mp. OR (vasectomy or sterilisation or sterilization or (tubal adj ligation)).mp OR ((vaginal adj ring) or cycletel or cycle-tel or abstain or abstinen* or lactational amenorr*).mp OR (pregnan* or abortion).mp OR exp Contraception/ OR exp Contraceptive Devices/ OR exp Pregnancy, Unplanned/ OR exp Pregnancy, Unwanted/ OR exp Abortion, Induced/ OR (NORPLANT or implanon or Femplant).mp. Limit to yr="1993-Current" and clinical trial, all

EMBASE via Ovid (date of search: 6 October 2014)

(phone adj3 call*).mp OR ((cell* or mobile or smart or Google or nexus or iPhone) adj3 (phone* or telephone*)).mp. OR smart- phone*.mp. OR smart-phone*.mp OR (blackberr* not extract).mp OR (black-berr* not extract).mp OR ((mobile adj3 health) not (van* or unit*)).mp. OR mhealth.mp OR m-health.mp. OR e-health*.mp. OR eHealth*.mp. OR (electronic adj health).mp OR (mobile adj3 technol*).mp. OR ((mobile or smartphone or smart-phone or phone or software) adj3 app*).mp OR MMS.mp. OR multimedia messaging service.mp OR SMS.mp OR short messag* service.mp. OR (text* adj messag*).mp OR text-messa*.mp. OR voice messag*.mp OR interactive voice response.mp. OR IVR.mp. OR Telemedicine/ OR cellular phone/ or text messaging/ AND (contracept* or (family adj planning) or (Birth adj control)).mp. OR condom.mp. OR (OC adj pill).mp. OR (depot medroxyprogest* or NET-EN or NET EN or Mesigyna or Cyclofem).mp. OR (intrauterine system or intra-uterine system or IUS or intrauterine device or intra-uterine device or IUD).mp. OR (vasectomy or sterilisation or sterilization or (tubal adj ligation)).mp. OR ((vaginal adj ring) or cycletel or cycle-tel or abstain or abstinen* or lactational amenorr*).mp. OR (pregnan* or abortion).mp. OR exp Contraception/ OR exp Contraceptive Devices/ OR exp Pregnancy, Unplanned/ OR exp Pregnancy, Unwanted/ OR exp Abortion, Induced/ OR (NORPLANT or implanon or Femplant).mp. Limit to yr="1993-Current", clinical trial, all and (clinical trial or randomized controlled trial or controlled clinical trial or multicenter study or phase 1 clinical trial or phase 2 clinical trial or phase 3 clinical trial or phase 4 clinical trial)

Cochrane Central register of Controlled trials (CENTRAL) (date of search: 6 October 2014)

((phone NEAR3 call*) OR ((cell* or mobile or smart or Google or nexus or iPhone) NEAR3 (phone* or telephone*)) OR (smartphone*) OR (smart-phone*) OR (blackberr* NOT extract) OR (black-berr* NOT extract)) OR ((mobile NEAR3 (health NOT (van* or unit*))) OR (mhealth) OR (m-health) OR (e-health*) OR (eHealth*) OR (electronic health) OR (mobile NEAR3 technol*)) OR ((mobile or smartphone or smart-phone or phone or software) NEAR3 (app*)) OR ((MMS) OR (multimedia messaging service) OR (SMS) OR (short messag* service) OR (text* messag*) OR (text-messa*) OR (voice messag*) OR (interactive voice response) OR (IVR))) OR exp Telemedicine OR exp Cellular Phone AND (((contracept*) OR (family planning) OR (Birth control)) OR (condom) OR ((OC pill)) OR ((depot medroxyprogest*) OR (NET-EN) OR (NET EN) OR (Mesigyna) OR (Cyclofem)) OR ((NORPLANT) OR (implanon) OR (Femplant)) OR ((intrauterine system) OR (intra-uterine system) OR (IUS) OR (intrauterine device) OR (intra-uterine device) OR (IUD)) OR ((vasectomy) OR (sterilisation) OR (sterilization) OR (tubal ligation)) OR ((vaginal ring) OR (cycletel) OR (cycle-tel) or (abstain) OR (abstinen*) OR (lactational amenorr*)) OR ((pregnan*) OR (abortion))) OR exp Contraception OR exp Contraceptive Devices OR exp Pregnancy, Unplanned OR exp Pregnancy, Unwanted OR exp Abortion, Induced Limit to 1993-2014

POPLINE (date of search: 6 October 2014)

Family Planning OR Pregnancy Unplanned OR Pregnancy Unwanted AND Cellular Phone OR Mobile Devices OR Text Messaging (1993-2014)

Africa-Wide Information (date of search: 6 October 2014)

((phone n3 call*) OR ((cell* or mobile or smart or Google or nexus or iPhone) n3 (phone* or telephone*)) OR (smartphone*) OR (smart-phone*) OR (blackberr* NOT extract) OR (black-berr* NOT extract)) OR ((mobile n3 (health NOT (van* or unit*))) OR (mhealth) OR (m-health) OR (e-health*) OR (eHealth*) OR (electronic health) OR (mobile n3 technol*)) OR ((mobile or smartphone or smart-phone or phone or software) n3 (app*)) OR ((MMS) OR (multimedia messaging service) OR (SMS) OR (short messag* service) OR (text* messag*) OR (text-messa*) OR (voice messag*) OR (interactive voice response) OR (IVR))

AND ((contracept*) OR (family planning) OR (Birth control)) OR (condom) OR ((OC pill)) OR ((depot medroxyprogest*) OR (NET-EN) OR (NET EN) OR (Mesigyna) OR (Cyclofem)) OR ((NORPLANT) OR (implanon) OR (Femplant)) OR ((intrauterine system) OR (intra-uterine system) OR (IUS) OR (intrauterine device) OR (intra-uterine device) OR (IUD)) OR ((vasectomy) OR (sterilisation) OR (sterilization) OR (tubal ligation)) OR ((vaginal ring) OR (cycletel) OR (cycle-tel) or (abstain) OR (abstinen*) OR (lactational amenorr*)) OR ((pregnan*) OR (abortion))

LILACS (date of search: 6 October 2014)

(contracept\$ OR family planning OR condom\$ OR pregnan\$ OR abortion\$) AND (phone\$ OR text

messag\$ OR mobil\$ health)

WHO international trials registry (date of search: 9 October 2014)

Condition (family planning) intervention (mHealth): (family planning OR contracept* OR pregnanc* OR abortion* OR condom*) AND (phone OR text messag* OR cellular phon* OR mobile phon* OR mobile devic* OR mobile technol*)

Current controlled trials

(family planning OR contracept* OR unplanned pregnanc* OR unintended pregnanc* OR induced abortion* OR condom*) AND (phone OR text messag* OR cellular phon* OR mobile phon* OR mobile devic* OR mobile technol*)

Acknowledgements

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Contributions of authors

Chris Smith and Caroline Free conceived of the review. Chris Smith oversaw the search and selection process, including the construction and implementation of search and quality appraisal strategies. He contacted authors of papers to ask for additional information from selected papers. Chris Smith and Colin Sumpter screened and selected studies and undertook data extraction. Judy Gold commented on selection of studies. Judy Gold and Caroline Free commented on risk of bias and assessment of behaviour change techniques. All of the review authors reviewed and commented on the review.

Declarations of interest

None known.

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- External sources: CS is supported by a Medical Research Council (MRC) Population Scientist Fellowship, UK.

Differences between protocol and review

In the protocol, we stated that we would assess risk of bias across the following domains: random sequence generation, allocation concealment, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other potential biases. In the review, we assessed risk of bias across the following domains in accordance with the latest version of the Cochrane Handbook for Systematic Reviews of Interventions: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias.

2.8 Randomised controlled trials identified subsequent to systematic review

Background

This section includes a review of trials of interventions delivered by mobile phone to support contraception use identified subsequent to conducting the searches for the systematic review in October 2014. It does not constitute an update to the systematic review as I have not replicated the search methods in Section 2.4. Trials discussed here have been identified by reviewing the on-going studies and additional relevant literature identified in Chapters 1 and 2, from MEDLINE (Ovid) auto-alerts, or by discussions with colleagues working in the field of interventions delivered by mobile phone to support contraception use. The long-term follow up from the MOTIF trial will be reported and discussed in Chapter 5.

Findings

Four ongoing studies were identified in the systematic review (Table 3). Evidence of subsequent reporting of results was sought by reviewing the clinical trials registry and contacting the study authors.

The Mobile for Reproductive Health (m4RH) service in Kenya has subsequently been evaluated with a randomised controlled trial.⁽¹⁹⁰⁾ New consumers who accessed the m4RH service were randomly assigned to either full access or limited access to m4RH on a rolling basis. Participants in the full-access group received information on benefits, disadvantages and side-effects of nine contraception methods, a searchable database of clinics offering family planning services and serial “role model” stories about a person facing a difficult family planning issue. Participants in the limited access group had access to the clinic locator along with general motivational messages on a variety of health topics, but no access to any other m4RH content. Outcome data was

assessed by sending questions by text message, with response rates to the surveys ranging from 13.5 to 51.8%. The authors reported that there was no differential loss to follow-up. Multiple imputation was used to impute missing data. Contraceptive knowledge increased by 14% amongst the full-access group compared to the limited access group (95% CI: 9.9%-18.2%). There was no difference in use of contraception between the two groups (79.7% full-access vs. 79.6% limited access; $p=0.94$). The authors concluded that text messages may increase family planning knowledge but do not, by themselves, lead to behaviour change.

If this paper were to be included in a subsequent systematic review, it is possible that it would be at risk of selection bias due to the sequence generation procedures, and attrition bias due to the amount of incomplete outcome data. Further limitations include that the study population comprised participants who had elected to enrol in the m4RH programme and thus might already have been motivated to use contraception. In addition, the intervention compared full access versus limited access to m4RH, but did not compare 'no access'. These limitations might have weakened the effect of the intervention.

Additionally, the m4RH programme have published a paper exploring strategies for mHealth programme sustainability using operational programme data considering three strategies for cost-recovery (user pay-for-service, text message cost reduction, and strategic partnerships) to develop four different cost-recovery scenarios.⁽¹³⁵⁾ In three of four scenarios, costs exceeded revenue. Breaking even was only possible in one scenario, in which the lowest text message rate was negotiated and users paid for all text messages sent or received. The authors commented that "*while this strategy*

was sustainable for the implementer, a central concern is that health information may not reach those who are too poor to pay, limiting the programmes reach and impact”.

Trial NCT01401816 was a pilot RCT (n=60) in the USA of a text messaging intervention to remind sexually active female adolescents to fill their prescription for emergency contraception.(191) The study authors report that the results will be published soon. (email communication with study author (T. Wilkinson), October 2016).

Trial NCT01545609 was a RCT (n=220) in the USA of a tailored text messaging intervention for inner city minority adolescent females aged 15-19 years wanting to start contraception and not on a method.(191) Half received an intervention comprising tailored text messages about their method of contraception and half received standard care. There was no difference in adherence, continuation and pregnancy between the intervention and control groups at four-months. However the intervention group was highly satisfied with the text and often shared messages with friends. Nonetheless, most did not continue their method (email communication with study author (J. Francis), January 2015). The results have not been published as of October 2016.

Trial NCT02093884 was a pilot RCT (n=100) in the USA of a text messaging intervention for adolescent females at high risk of pregnancy in the emergency department who are potential users of contraception.(192) The study authors plan to submit for publication in the next few months (email communication with study author, (L. Chernick) October 2016).

Additional ongoing trials

Two additional trials assessing interventions delivered by mobile phone are ongoing.

A RCT assessing automated voice messages linked to telephone counselling to increase post-menstrual regulation contraceptive uptake and continuation (n=969) is being undertaken in Bangladesh.(193) RCTs assessing interventions delivered by mobile phone by text message or instant messaging to increase the acceptability of effective contraception among young women are being undertaken in Palestine, Tajikistan and Bolivia.(194)(195)(196)

Additional literature

With regards to other opt-in text message services that provide information on contraception identified in section 1.6, it was not evident that the Mobile Alliance for Maternal Action (MAMA), FamPlan, CycleTel or MyPill initiatives had subsequently been evaluated with randomised controlled trials. A formative research report to inform “Aponjon”, the Bangladesh version of MAMA, which provides health information by mobile phone to expectant and new mothers, found that the majority of participants choose to receive voice messages rather than text messages. However, it was not clear from the report whether contraception messages were included in the intervention.(197)

The mAssist trial, mentioned in section 1.6, was a text message intervention to support the home phase of medical abortion in South Africa and was demonstrated to reduce women’s anxiety and stress.(178) Increased uptake of long-acting reversible contraception (21% intervention vs. 13% control) was reported in a project brief,(198) but the study author reported that the PAFP data was not rich enough to constitute a stand alone paper (email communication September 2014).

Conclusions

Only one of the previously identified ongoing trials has reported results, the m4RH evaluation. However this trial had several limitations and it does not alter the conclusion of the systematic review that further high quality trials are required to robustly establish the effects of interventions delivered by mobile phone to increase contraception use. There are several ongoing trials and a repeat systematic review could be considered in one or two years.

3. Development of a mobile phone-based intervention to support contraception use in Cambodia

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS

SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	Reproductive Health journal. Citation: Smith C, Vannak U, Sokhey L, Ngo T, Gold J, Free C. Mobile Technology for Improved Family Planning (MOTIF): the development of a mobile phone-based (mHealth) intervention to support post-abortion family planning (PAFP) in Cambodia. Reprod Health [Internet]. Reproductive Health; 2016;13(1):1–8. Available from: http://dx.doi.org/10.1186/s12978-015-0112-x		
When was the work published?	2016 (Accepted: 18 December 2015)		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Yes. It is Open Access and the article is distributed under the terms of the Creative Commons Attribution 4.0 International License which permits unrestricted use, distribution and reproduction in any medium. The work is not being included in its published format (it has been converted to Word format, tables and figures have been re-created, as per the rest of the thesis). The journal has given permission for this work to be included in the thesis (see Appendix 5)	Was the work subject to academic peer review?	Yes

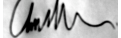
****If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (published or other author) to include this work.***

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the first author on this paper. I was responsible for designing the interview and focus group topic guides, conducting the analysis and drafting the manuscript. My co-authors supported this work in an advisory capacity and helped to edit the writing.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

Chapter transition notes

The systematic review (Chapter 2) found limited evidence for interventions delivered by mobile phone to increase contraception use. This chapter (Chapter 3) is a research paper describing the intervention development for the MOTIF trial. This paper reviews literature on determinants of contraceptive use, behaviour change theory, interventions delivered by mobile phone in other areas and interventions for improving contraception use. The paper includes a case note review of clinic data, interviews and focus groups with women seeking abortion services and consultation with clinicians and local organisations implementing mHealth activities and presents a conceptual framework for the intervention.

Mobile Technology for Improved Family Planning (MOTIF): the development of a mobile phone-based (mHealth) intervention to support post-abortion family planning (PAFP) in Cambodia

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3.1 Abstract

Background

The objective of this paper is to outline the formative research process used to develop the MOTIF mobile phone-based (mHealth) intervention to support post-abortion family planning in Cambodia.

Methods

The formative research process involved literature reviews, interviews and focus group discussions with clients, and consultation with clinicians and organisations implementing mHealth activities in Cambodia. This process led to the development of a conceptual framework and the intervention.

Results

Key findings from the formative research included identification of the main reasons for non-use of contraception and patterns of mobile phone use in Cambodia. We drew on components of existing interventions and behaviour change theory to develop a

conceptual framework. A multi-faceted voice-based intervention was designed to address health concerns and other key determinants of contraception use.

Conclusions

Formative research was essential in order to develop an appropriate mHealth intervention to support post-abortion contraception in Cambodia. Each component of the formative research contributed to the final intervention design.

3.2 Introduction

Cambodia is one of the poorest and least developed countries in Asia. Eighty percent of Cambodians live in rural areas, 45% are under the age of 20 and approximately 28% live below the poverty line. Despite recent improvements in health indicators, maternal mortality remains high at 206 deaths/100,000 live births.⁽⁷⁷⁾ Although the total fertility rate declined to 3.0 births per woman in recent years, there remains unmet need for contraception. The 2010 Cambodia Demographic and Health survey (DHS) reported that although 81% of women of reproductive age wanted to delay their next child or have no more children, only 35% reported using a modern contraceptive method.⁽⁷⁷⁾

The abortion rate in Cambodia has been estimated to be 50/1,000 women, compared to the global average of 28/1,000.⁽⁸⁰⁾ As fertility can return within two weeks it is important to start contraception as soon as possible after abortion if the woman wants to prevent subsequent unintended pregnancies.⁽⁶⁾ In Cambodia, amongst women who have had an abortion, 26% have had more than one.⁽⁷⁷⁾ This suggests there is a need to improve contraception uptake and continuation post-abortion.

Mobile phone-based interventions ('mHealth') refer to the use of mobile technologies for health.⁽¹¹²⁾ mHealth interventions can utilise different modes of communication;

for example, text-message, voice messages, video and smartphone applications and may involve one-direction or two-way (interactive) communication.(116) mHealth interventions can deliver support inexpensively wherever the person is located, whenever it is needed. In particular, mHealth has the potential to reach out to youth and rural populations, where geographical distances can restrict access to services.(115)

Although a number of mHealth contraception initiatives have been launched and scaled up in low-income settings, to date, the effect of mHealth interventions on post-abortion family planning PAFP have not been reliably established. There is therefore a need for more evidence on the effectiveness of mHealth interventions for PAFP. Formative research is often used to design context-specific interventions. It may involve literature reviews and research with the target population and other key stakeholders.(199) However, the process is rarely reported.(200) This paper outlines the formative research process we used to inform development of the MOTIF intervention to support PAFP in Cambodia.

3.3 Methods

The MOTIF study was conducted at four Marie Stopes International Cambodia (MSIC) clinics providing comprehensive sexual and reproductive healthcare services; two serving predominantly urban populations around Phnom Penh City, and two serving predominantly rural populations (Battambang and Siem Reap). Ethical approval was granted by the LSHTM ethics committee, the MSI ethics committee and the Cambodia Human Research ethics committee.

Development of the MOTIF intervention was iterative and included processes recommended for the development of complex interventions.(201) We drew on

existing knowledge and reviewed literature (using simple keyword searches) in the following areas with particular reference to Cambodia; determinants of contraceptive use, behaviour change theory, interventions delivered by mobile phone in other areas; interventions for improving contraception use.

Research conducted in Cambodia included a case note review of clinic data, interviews and focus groups discussions (FGD), consultation with clinicians and local organisations implementing mHealth activities, development of a conceptual framework, and testing the intervention with the target group.

The case note review of 100 MSIC abortion clients was conducted during October and November 2012 using routinely collected data to estimate baseline event rates. We identified the first 25 clients seeking abortion services at each of the four clinics attending sequentially from 1st September 2011 from the clinic register. Repeat attendances over subsequent 12-months were identified. Where available, data was collected on age of client, residence, provision of a mobile phone number, contraceptive history, reason for abortion, subsequent follow-up attendances, contraceptive use and abortions. The data was summarised using simple statistics. Table 10 contains a summary of characteristics of clients from the case note review, interviews and FGDs.

Following the case note review we conducted interviews and FGDs with clients seeking abortion services. Clients attending for abortion services were recruited sequentially by research assistants for both the interviews and FGDs. Potential participants were asked if they would like to participate at the end of their post-abortion counselling session. Clients were provided with an information sheet to read, or it was read to them, and provided signed or thumb-printed consent. Clients were either interviewed

Table 10: Characteristics of case note review clients and interview and focus group discussion participants

Characteristics of 100 case note review clients				
Age (years)	Average	29.3		
	Range	18-46		
	<25	28 (28%)		
	25 or above	72%		
Employment status*	Employed	10 (10%)		
	Factory worker	22 (22%)		
	Self-employed	12 (12%)		
	Farmer	23 (23%)		
	Entertainment worker	2 (2%)		
	Housewife	31 (31%)		
Martial status**	Married	100 (100%)		
*Self-reported employment status according to MSIC client registration form. Categories may not be mutually exclusive				
**It is possible that women do not disclose being single given that pregnancy outside of marriage is not socially acceptable in Cambodia				
Characteristics of focus group discussion (FGD) participants				
FDG	Location	Participants		
1	Urban	Two participants. Limited data on clients that agreed but then did not join		
2	Urban	Three participants. Conducted on a Sunday. Possible that more factory workers may have attended this group		
3	Rural	Six participants: all mainly users of PAFP and older women		
4	Rural	Five participants: non-users of PAFP and younger if compared to CBB		
Characteristics of interview participants				
No.	Age	Occupation	Marital status	Clinic
1	20	Factory worker	Married	Urban
2	32	Business	Married	Urban
3	21	Company staff	Married	Urban
4	26	NGO staff	Married	Rural
5	26	Housewife	Married	Rural
6	26	Business (sells clothes)	Married	Rural
7	30	Business	Married	Rural
8	36	Farmer-migrant	Separated	Rural
9	21	Student	Married	Rural
10	26	Student-employment	Married	Rural
11	28	Factory worker	Separated	Urban
12	20	Factory worker	Married	Urban
13	34	Factory worker	Married	Urban
14	31	Factory worker	Married	Urban
15	24	Working in bank	Married	Urban

at the time of attending for abortion services or when attending for follow-up appointment, according to their preference.

Author UV conducted 15 semi-structured interviews with clients during December 2012 and January 2013 across the four study clinics by in the Khmer (Cambodian) language. A topic guide was developed containing questions to explore clients' reasons for seeking abortion services, contraception and mobile phone use and to seek views on the proposed intervention (see Table 11).

Table 11: Interview and focus group discussion topic guides

<p>Interview topic guide</p> <p><i>Demographics:</i> Questions about age, residence, distance from clinic, literacy</p> <p><i>1) Views on current service</i></p> <ul style="list-style-type: none"> You have recently used the Marie Stopes services. Could you tell me about your experience of the services? What information did they give you about contraception? What did you think about any advice they offered about contraception? <i>Prompt for:</i> any counselling offered, acceptable tone, content of information, relevant? What method did you use? What different methods of contraception did the staff inform you about? Were the staff able to answer all of your questions? Did the staff arrange follow up? Have you used the Hotline service at MSI? <i>If yes:</i> could you tell me about your experience of using this service? <i>Prompt for:</i> If you experienced unexpected effect's from contraception what advice were you given? Any comments about privacy and confidentiality when discussing contraception over the phone? Do you have any suggestions for improvement? <i>If no:</i> any reason for this <p><i>2) Contraception use</i></p> <ul style="list-style-type: none"> Have you ever used contraception? <i>If yes:</i> when was the last time you used contraception? Which method? What was your experience of taking contraception? <i>If discontinued:</i> Why did you stop it? Any unexpected-effects? Did you seek advice, if so from whom? Have you ever used other methods of contraception? (<i>if yes, repeat above questions</i>) <i>If using contraception when became pregnant:</i> Why do you think you became pregnant even whilst you were using contraception? (probe for missed pills diarrhoea, or other cause of contraceptive failure) Where would you obtain contraception usually? Motivation for using contraception? <i>If no:</i> any reason for this? What are your current plans for contraception? Ideally, where would you go to get contraception? <i>Probe on</i> community based, fixed clinic, private provider <i>and</i> why? Do you have any children? How many? Desired family size? <p><i>3) Reasons for abortion</i> If not already raised:</p> <ul style="list-style-type: none"> When did you realise you were pregnant? Had you wanted to be pregnant? <i>Prompt for:</i> Reasons for abortion (e.g. medical, social)? Discussed with others? <p><i>4) Views on the intervention</i></p> <ul style="list-style-type: none"> What do you think about receiving text messages or phone calls relating to contraception? <i>Prompt for:</i> preference for phone/text, types of message, frequency, language

Mobile phone usage

- Do you have access to a mobile phone?
If yes: Prompt for: Network, type of phone, Smartphone. Do you own the phone?
- How do you use your phone? *Prompt for: SMS/phone call/internet/preferences*
If no: Prompt for: Any reasons why not? Any future plans to get phone?

Can I finally ask you for any final comments that have not been covered in this interview. Thank you very much for helping us and giving up your time

One-month follow-up phone call

- How are you? Is this a suitable time for you to talk?
- Are you currently using a contraceptive method?
If yes: which method? How are you taking it? Any problems?
If no: any reason for this? If a method discontinued: Why did you stop it? Any unexpected-effects? Did you seek advice, if so from whom?
- What are your future plans for contraception?

Do you have any other comments? Thank you very much for helping us and giving up your time

FGD topic guide

Mobile phone use

- Do you have a mobile phone? Is it your own phone or shared? Who pays for credit?
- How do you use your phone? Preference for SMS vs. Phone (including voicemail)
- Literacy: read or write Khmer or English?
- Privacy/confidentiality: does anyone else have access to your phone (either answer the phone or check SMS messages)? Is this a problem? Are you able to make calls in private?

PAFP

- Current/future plans for contraception and pregnancy. Reasons for use/non-use; where do you plan to go to get contraception in the future?
- Disclosure to others about contraception use (?also abortion); reasons

Views on the proposed new service

- Would you be interested in receiving a service provided by MSI to provide support via your mobile phone for contraception after abortion?
- Do you have any suggestions for this service?
- Any comments if we were sending you sensitive messages or discussion about contraception over the phone? Would this be a problem?
If relevant: would you still be interested in the service even if you haven't decided to use contraception at the current time?

Scenarios

(1) Regular communication from MSI to client to check for any problems or provide info

- Comments on this
- SMS or phone?
- Automated message vs. having a 'real time' conversation
- If a pre-recorded voice message (or SMS) do you have any suggestions as to what the message could say?

If no suggestions ask for feedback on the following 3 messages and which one they prefer:

1. "Hello, how are you? This is a message from Marie Stopes to check how you are doing. Press 1 if you are fine, or 2 if you have a problem and we will call you back"
2. "Hello, how are you? This is a message from Marie Stopes to check how you are doing. If you have any questions for us please leave a message after the beep and we will respond to you with an automatic message within 2 days"
3. "Hello, how are you? This is a message from Marie Stopes to check how you are

with regards to contraception. Press 1 if you are fine, or 2 if you have a problem.”
If client presses 2, then the client receives a series of options asking what the problem is 1,2,3,4,5 etc. to identify and provide a response straight away

- Any comments on whether we should mention ‘Marie Stopes’ or ‘contraception’ or your name in the message?
- If a VOICE message asked for a response e.g. Press 1 if you are fine, or 2 if you have a problem, would you be able to do that? Would you be able to leave a voice message so that we can respond later?
- If a simple SMS (e.g. OK?) that required the client to press 1 if you are fine, or 2 if you have a problem, would you be able to do that?
- Comments on the frequency of messages to clients?

(2) Side-effect from contraception (example irregular bleeding, headache from pill or depot)

- What would you do? Would you consider phoning the new service for advice? What if this involved the cost of a local call? (explain this might make the service more ‘sustainable’)
- Views on automated response (and able to leave a message) vs. having a ‘real time’ conversation (explain automated might also make the service more ‘sustainable’)
- Views on instant response vs. delay of 1-2 days
- How about if we linked you up with another client using a method to share experience? Would you mind sharing experience as a ‘model client’?

(3) Daily pill reminder (additional service if using pill)

- Opinions on this; SMS vs. phone. What could that message say? (e.g. *OK PILL*)
- Or for calendar method?

(4) Appointment reminder

- Opinions on this; SMS vs. phone. What could that message say? (e.g. *Marie Stopes appointment 1 week*)

(5) Problem after abortion e.g. bleeding or pain

- Opinion on phone call or SMS a few days or a week after abortion to ask how the client is after abortion (as well as asking about contraception)

(6) Other scenarios?

- Any other suggestions? Any other information that clients would like to receive via mobile phone?
- Based on our discussion about how we might provide the service, how long do you think we should provide this service to clients after they have an abortion?

Summing up

- Summarise key points raised in the FGD
- Ask if anything has been missed or participants want to add anything

Clients were contacted for a follow-up phone interview after one month. There were three refusals because clients stated that they didn’t have time. Interviews were recorded and transcribed into English and read by author CS to identify key themes.

Four FGDs were conducted during January and February 2013; two at urban clinics, and two at rural clinics. The aim of the FGDs was to test proposed messages, seeking clients’ feedback and suggestions for improvement. The FGD topic guide was informed by the interviews. FGDs were conducted by authors CS and UV and a summary of the

discussion transcribed to English. Transcripts were read by CS to identify key themes. These findings were used to guide intervention development. We also consulted with other organisations implementing mobile phone-based interventions in Cambodia. We developed a preliminary intervention based on these activities. The messages were then tested with eleven interview and FGD participants who agreed to receive messages on their mobile phones. Messages were modified based on feedback received on content, tone, speed of voice, and sound quality.

3.4 Results

Literature on determinants of contraceptive use, with a focus on Cambodia

We reviewed literature on determinants of contraceptive use in order to identify areas amenable to an intervention. We found Sheeran's framework to be useful as it combines developmental models (describing contraceptive use resulting from transition through a series of stages) and decision-making models (psychological factors that speed up or delay this transition). Sheeran's framework considers contraceptive use as a product of *background, intrapersonal, interpersonal* and *situational* factors.(50) The 2010 Cambodia DHS collected data on *background* factors associated with contraceptive use reporting increased contraceptive use with increasing parity, wealth, and levels of educational attainment.(77) Westoff conducted additional analysis on *intrapersonal, interpersonal* and *situational* reasons for non-use of contraception.(3) Globally, health concerns including side-effects are the commonest reasons for non-use of contraception; this is particularly evident in Cambodia, with health concerns accounting for almost 50% of non-use of contraception.(3)(16)

We identified qualitative research supporting these findings. Experience of negative

side-effects may be related to traditional health beliefs in Cambodia.(78) Petitet and Desclaux reported that in Cambodia, abundant menstruation (the expulsion of 'bad blood') is viewed as a sign of good health and fertility. Contraceptive methods that result in reduced menstruation can cause women to worry about blood retention leading to discontinuation.

Dingle identified factors related to knowledge, access, cost and autonomy as important reasons for non-use of contraception in Cambodia. Women often obtain information about contraception from friends and relatives, with myths and rumours commonplace.(79) Furthermore, not all women have full autonomy over health care decision-making. The Cambodia DHS reported that only 45% of married women make their own decisions about health care.(77) Sex workers in Cambodia have even less autonomy, often reporting coercion by clients into unprotected sex.(91) Finally, access and cost can influence choice of contraceptive method, particularly for poor women living in rural areas. Women have to consider the opportunity cost of travelling to provincial towns to obtain contraceptive methods.(79)

Behaviour change theory

Lopez highlighted the need for increased attention to theory of behaviour change in designing and evaluating interventions for contraception use.(99) In addition to understanding existing contraceptive behaviour, we drew on behaviour *change theory*. Michie defined 'behaviour change interventions' as '*coordinated sets of activities designed to change specified behaviour*' and developed a taxonomy of behaviour change techniques included in interventions, for example provision of information on risks, consequences of actions, or conversely, encouragement and goal setting.(100) We applied this framework as its development involved a systematic literature review,

evaluation of existing frameworks and reliability testing. At its core, a 'behaviour system' involving three essential conditions; *capability* (an individual's psychological and physical capacity to engage in the activity), *motivation* (the brain processes that direct behaviour which include conscious decision-making and emotional responding) and *opportunity* (factors that lie outside the individual that make behaviour possible).(100)

Literature on interventions delivered by mobile phone in other areas

We reviewed evidence from systematic reviews of mHealth interventions. Free, et al.'s systematic review of mHealth interventions found that there is currently no evidence of benefit for simple text-message medication reminders (RR 1.00, 0.77–1.30).(115) This is consistent with existing adherence research demonstrating that multifaceted interventions can be effective but uni-faceted interventions have modest benefits.(134)

Multi-faceted mHealth interventions have been shown to increase smoking cessation in a high-income setting and adherence to HIV medication in a low-income setting.(123)(125) Of particular interest was the WeTel trial in Kenya, evaluating a multi-faceted intervention for HIV medication adherence.(127) Participants were sent a weekly text-message in the local language asking, "How are you?" Therefore if the message was seen by a third person it was not obvious that that it was sent from a HIV clinic. Health workers would then phone clients who reported a problem. Medication adherence was higher in the intervention group, demonstrating that an mHealth intervention could be effective when confidentiality and privacy are important.

Literature on mHealth in Cambodia

We found limited published literature on mHealth in Cambodia although Cambodians are enthusiastic mobile phone users, as can be witnessed during daily life in both urban and rural areas. Although mobile phone ownership is estimated to be over 90%, most Cambodians use simple rather than internet-enabled smartphones.(202) There is significant interest in mHealth in Cambodia among an increasing number of organisations.

Bullen identified a number of operational challenges facing mHealth programmes in Cambodia.(141) Cambodian mobile phone users often have multiple Subscriber Identification Module (SIM) cards and share phones, which can make it difficult to maintain contact with users. Cambodians often prefer to use their mobile phone for voice calls rather than text-messages as many phones lack Khmer language capability. Furthermore, whilst literacy levels are 90% in urban areas, this figure is lower (69%) in rural areas.(77)

Literature on interventions for contraception including those delivered by mobile phone

We next reviewed literature on behaviour change interventions to increase contraception use. Systematic reviews have found limited evidence for interventions to improve contraception and PAFP.(92)(93) We identified three trials of mHealth interventions aimed at increasing use of contraception, all evaluating text message interventions. The two trials that did not show an effect both evaluated simple uni-faceted text message interventions (contraception reminders).(143)(144) The intervention that was effective comprised a variety of daily educational text messages and oral contraceptive (OC) reminders.(142)

Other mHealth contraception initiatives that have been launched and scaled up in low-income settings include Mobile for Reproductive Health (m4RH) and Mobile Alliance for Maternal Action (MAMA). m4RH used best practices from health communication programs to systemically develop family planning text messages and MAMA developed adaptable messages based on WHO and UNICEF guidelines.(146)

Findings from the case note review

The case note review found uptake of effective PAFP either immediately after abortion or at two-week follow-up to be 40% (n=40) (OC, intra-uterine device, implant, injection). Over 50% of clients did not return to the MSIC clinic for any reason within 12-months of having an abortion. 4% of clients returned to the same clinic for repeat abortion within 12-months with 8% returning with repeat pregnancy. Over 80% of clients provided a mobile phone number.

Findings from the interviews and FGDs

Interview and FDG participants reported seeking abortion services for mainly economic, or less commonly, health reasons (Table 12). Most women reported disclosing having an abortion with their husband or partner. Many women reported side-effects when using contraception in the past. Clients reported it was difficult to make PAFP choices at the time of abortion. Reasons for this included wanting to wait for their health to improve first, having to wait for their salary or needing to discuss with their husband. Some women reported they were unable to retain sufficient information about contraception they were given. When we contacted clients for the one-month post-interview phone call they often had many questions relating to contraception and side-effects.

Table 12: Quotes from interviews and focus group discussions with clients

Related to current abortion
<i>"If we want to have more children, those who go to school must drop out because we have no enshrined money for their study"</i> (age 30, married, two children)
<i>"We do not have enough money yet...my husband stays far away from me...he always goes to province"</i> (age 24, married, no children)
<i>"I discussed with my husband. He said just do what I want to do"</i> (aged 34, married, one child)
Reported previous experience with contraception use
<i>"I wasn't using it regularly so I got sick because of it...it felt hot inside my chest and I felt exhausted... Thus I changed to condom but difficulty is it enables cervicitis"</i> (aged 34, married, one child, talking about previous experience with OC)
<i>"Because we feel so tired after coming back from the business and we don't take it regularly or maybe we forget to take it one evening, so we're lazy"</i> (aged 30, married, two children talking about previous experience with OC)
<i>"Husband heard from a friend that 'when we use condom a girl can be burned, it is not good for both husband and wife'. So I followed my husband"</i> (aged 24, married, no children, talking about previous contraception use)
Reported factors influencing use of post-abortion family planning
<i>"I am not able to afford any of these methods to prevent pregnancy. If I could afford I would practice the contraceptive method...I think I might wait for my monthly salary"</i> (aged 28, separated, no children, talking about PAFP)
<i>"Not interested in contraception yet...because my health is not so good"</i> (aged 21, married, talking about plans for PAFP)
<i>"She told me a lot but I forgot some because there're a lot of methods"</i> (aged 26, married, no children, talking about PAFP counselling received)
Reported mobile phone use
<i>"Even when the company sends messages we can't read and leave alone the messages sent"</i> (aged 30, married, two children)
<i>"I don't really understand the message in the phone"</i> (aged 34, married, one child)
<i>"My older sister sent a message and I got my husband to read it"</i> (aged 30, married, two children)
<i>"Husband pays bill but never picks up my phone to answer"</i> (aged 26, married)
Views on the intervention
<i>"I think its good because we need contraceptive method to prevent pregnancy, so we need some advice to do this or that"</i> (aged 31, married, no children)
<i>"Such as service is really good...for women and their health and there can be a lot of side-effects if they have frequent abortions...it means they take care of us"</i> (aged 21, married)
<i>"We talk on phone, no-one knows our face...If anyone said that they saw us drive here, they would think that we didn't come here to discuss but to do something, so if we have this programme I think that its very good...it makes clients reduce the time to come directly"</i> (aged 26, married, no children)
<i>"We are ignorant and cannot read the messages so we leave them we see them, so I suggest talking directly with each other"</i> (aged 30, married, two children)

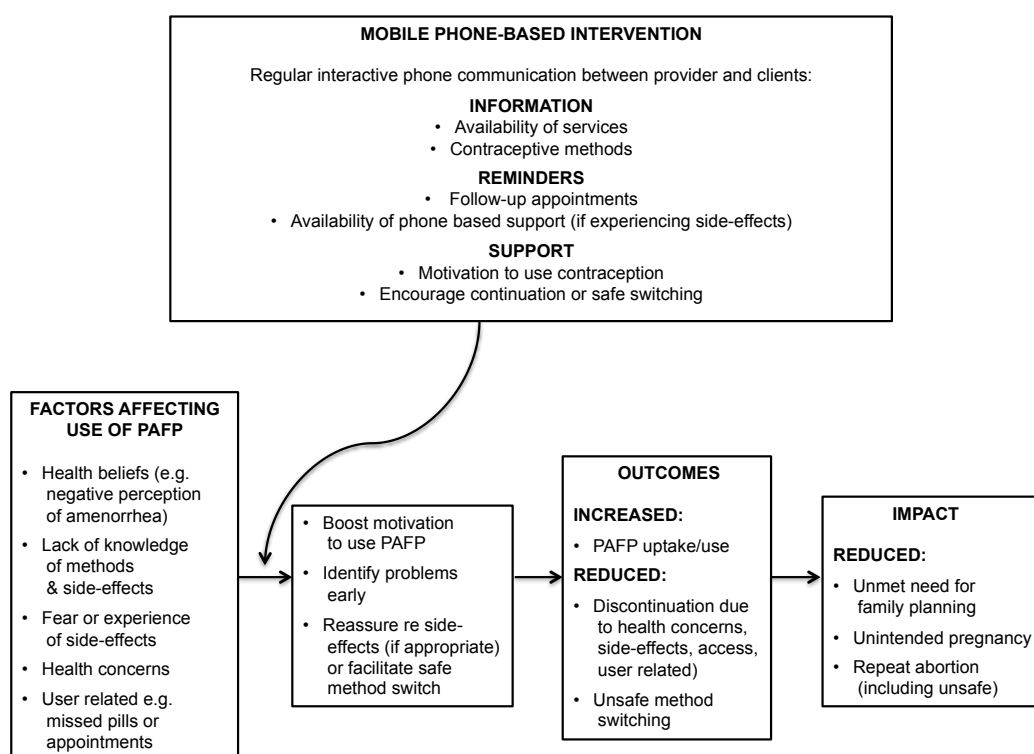
Regarding the proposed mHealth intervention, most clients said they preferred to make phone calls over text message. Most clients could not read and many had never used text messaging. However, most clients reported listening to voice messages

received on their phones. All clients were positive about the proposed new MOTIF intervention. Despite sharing of phones, privacy was not mentioned as a particular concern. Most clients stated that messages sent to their phones should mention the terms ‘Marie Stopes’ and ‘contraception’ so they would know the topic of the message and who it was from. Consultation with clinic staff and organisations implementing mHealth activities in Cambodia also suggested a limited likelihood of success with a text-message intervention.

Developing a conceptual framework and the final intervention

We developed a conceptual framework (Figure 30) for the intervention that considered determinants of contraceptive use, links between contraceptive use and fertility and theory of behaviour change.

Figure 30: Conceptual framework for the MOTIF intervention in Cambodia



There is an emphasis on addressing *intrapersonal* factors, in particular health concerns. The intervention aimed to improve clients *capability* to use contraception by

providing information about contraceptive methods, *opportunity* to use contraception i.e. informing clients where they can access contraception near to where they live, and *motivation* by re-enforcing the benefits of contraception use and providing support relating to side-effects.(100)

We tested the messages with clients and made final modifications based on their feedback. See Table 13 for a description of the final intervention.

Table 13: Final MOTIF intervention

The MOTIF final intervention comprised a series of automated voice messages to participants' mobile phones over the three-month period following their abortion, at the time of day of their preference. Clients received the first message within one-week of receiving abortion services and then every two-weeks, with a total of six messages. The main message, recorded in the Khmer language, was as follows:

'Hello, this is a voice message from a Marie Stopes counsellor. I hope you are doing fine. Contraceptive methods are an effective and safe way to prevent unplanned pregnancy. I am waiting to provide free and confidential contraceptive support to you. Press 1 if you would like me to call you back to discuss contraception. Press 2 if you are comfortable with using contraception and you do not need me to call you back this time. Press 3 if you would prefer not to receive any messages again'

Clients who pressed 1, or who did not respond to the message prompts, received a phone call from a counsellor. The phone calls aimed to support contraceptive use by addressing clients' *capability* to use contraception by providing individualised information on a range of contraceptive methods, *opportunity* to use contraception e.g. informing clients where they could access specific methods near to their residence, and *motivation* by re-enforcing the benefits of contraception use. If the client requested, the counsellor would also discuss contraception with the husband or partner. Follow-up calls to clients were made during preferred times indicated by the client on her registration form. Clients were also able to call the MOTIF service at any time to request to speak with a counsellor. Clients that chose to receive the OC or injectable could opt to receive additional reminder messages appropriate to their method (e.g. to start a new packet of pills or when to receive a new injection). The sixth and final voice message provided similar information to the first five, but also reminded the client that this would be the last message they will receive.

The MOTIF intervention was delivered by trained counsellors at the MSIC head office in Phnom Penh. Voice messages were scheduled and sent using the open-source software programme 'Verboice', developed by InSTEDD (instedd.org). MSIC incurred the cost of outgoing communication from the provider to client, and clients incurred any costs calling into the service (the cost of a local call).

Table 14 summarises how formative research findings contributed towards the intervention design.

Table 14: Implications of key formative research findings for intervention design

Formative research component	Key findings	Implication for intervention design
Insights from contraception literature	<ul style="list-style-type: none"> Health concerns identified as major reason for non-use. Other reasons include factors related to access, cost, autonomy Limited evidence for interventions to improve adherence to specific contraceptive methods or uptake of PAFP Most discontinuation occurs within the first few months 	<ul style="list-style-type: none"> Intervention needs to address health concerns as well as factors related to access, cost (by informing clients where they can access contraception near their home) and autonomy The intervention needs to anticipate some discontinuation and aim to facilitate safe method switching and well as support continuation with existing method Decided to provide intervention for three-months
Insights from mHealth intervention and behaviour change literature	<ul style="list-style-type: none"> Uni-facteted adherence interventions have at best modest effects A semi-automated mHealth intervention increased adherence to HIV treatment in Kenya 	<ul style="list-style-type: none"> Developed a multi-faceted intervention providing information reminders and support to boost motivation to use PAFP A similar intervention could be adapted for PAFP in Cambodia
Case note review	<ul style="list-style-type: none"> 40% uptake of effective PAFP at the time of seeking abortion services Over 50% clients did not return to the clinic within 12-months 	<ul style="list-style-type: none"> An mHealth intervention is an opportunity to maintain contact with clients that don't return to the clinic for contraception after seeking abortion services
Interviews	<ul style="list-style-type: none"> Side-effects with contraception common Clients can find it difficult to make decisions about PAFP at time of seeking abortion services Women sometimes have to discuss with their husband/partner before using contraception 	<ul style="list-style-type: none"> Re-enforced findings from literature that intervention should address health concerns The mHealth intervention is an opportunity to maintain contact and remind clients about available methods Re-enforced findings from literature review that the intervention take into account women's lack of autonomy, facilitating a discussion with husband/partner if appropriate
Focus group discussions	<ul style="list-style-type: none"> Preference for voice rather than text-based intervention Many clients preferred direct phone call to automated message Clients preferred that the messages mentioned the terms 'Marie Stopes' and 'contraception' 	<ul style="list-style-type: none"> Intervention used voice messages sent to clients phone instead of text-messages Developed a semi-automated intervention as fully counsellor delivered intervention would be costly to scale up Voice message mentioned 'contraception' and 'Marie Stopes', but not the name of the client
Consultation with MSIC staff and other	<ul style="list-style-type: none"> Text-message interventions likely to have limited success in 	<ul style="list-style-type: none"> Re-enforced findings from clients that intervention should use voice

organisations	Cambodia	rather than text
	<ul style="list-style-type: none"> • A fully counsellor delivered intervention would be costly and hence harder to scale-up 	<ul style="list-style-type: none"> • Intervention was semi-automated aiming to identify clients most in need of additional support

* A unifacted interventions refers to single-component intervention. A multi-faceted intervention refers to a complex intervention using a range of behaviour change techniques

3.5 Discussion

We used a wide range of methods to inform the development of the MOTIF intervention. Our literature review indicated that our intervention should address intrapersonal factors, in particular health concerns. We found limited evidence on behaviour change interventions to increase the use of specific contraceptives. Whilst this may be partly due to a limited number of high quality, adequately powered trials, the focus of the interventions needs to be examined. Interventions often focus on adherence to a specific method, which may be less effective than an intervention that anticipates method-specific discontinuation and facilitates safe method switching.(16)

We designed an intervention to offer to all women seeking abortion services, regardless of the immediate plans for PAFP.

A key finding from the case note review was high unmet need for PAFP. It was not known if clients used other providers to obtain contraception as most women did not return to MSIC clinics. Most clients provided a mobile phone number, which led us to believe that a mHealth intervention could be an opportunity to maintain contact with clients. Interviews and FGDs supported these findings. Health concerns related to contraception were widely reported. Clients also stated a clear preference for a voice-based intervention. In developing the conceptual framework and intervention we hypothesised that a multi-faceted mHealth intervention would remind clients about contraceptive methods, identify problems with side-effects early, provide support, and boost motivation to use PAFP, while reducing discontinuation and method switching.

The strength of this paper is that we have clearly described how each component of the formative research contributed to the final intervention design. Interventions are often developed without evidence of having gone through a formative research process or without clearly describing what activities the formative research involved. Furthermore, existing behaviour or theoretically predicted mechanisms of action are not fully described.(200)(100) Our research allowed us to gain an understanding of what types of interventions had been successful, and to avoid repeating mistakes of unsuccessful projects. Our limitations were mainly due to time and resource constraints. A limitation of our formative research is that analysis of the interviews and FGDs was not undertaken by a second coder. Furthermore, the literature searches were not systematic. However, as interventions can always be improved, it is important to consider when to stop the development process.(200) The formative research period including obtaining ethical approval was seven-months.

Using a similar approach to Lester et al, we developed a semi-automated intervention, which sought to identify clients most in-need of counsellor delivered support.(127) Where the MOTIF intervention differs from Lester and other mHealth contraception interventions is that it is voice-based. The main reasons for this were rural literacy levels, lack of functionality of Khmer script on phones, and client preference. This study provides some insights into mobile phone-based interventions intervention development in low-literacy settings.

The MOTIF intervention was associated with an increase in self-reported contraception use four months post-abortion but not at 12 months. The intervention was associated with increased long-acting⁶ contraception use at four and 12 months.(167)(203) A

⁶ Intrauterine device, implant or permanent method

process evaluation will explore participants' experience and cost comparison of MOTIF with other interventions.

Competing interests

The authors declare that they have no conflict of interest.

Authors' contributions

CS and CF designed the intervention and the trial. CS drafted the manuscript. UV and LS assisted with formative research to develop the intervention. JG, TN and CF helped to draft the manuscript. All authors read and approved the final manuscript.

Acknowledgments

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4. MOBILE Technology for Improved Family Planning Services (MOTIF): study protocol for a randomised controlled trial

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS

SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	Trials journal. Citation: Smith et al.: MOBILE Technology for Improved Family Planning Services (MOTIF): study protocol for a randomised controlled trial. Trials 2013 14:427.		
When was the work published?	Received: 30 August 2013 Accepted: 5 December 2013 Published: 12 December 2013		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Yes. It is Open Access and the article is distributed under the terms of the Creative Commons Attribution License which permits unrestricted use, distribution and reproduction in any medium provided the work is properly cited. The work is not being included in its published format (it has been converted to Word format, tables and figures have been re-created as per the rest of the thesis). The journal has given permission for this work to be included in the thesis (see Appendix 5)	Was the work subject to academic peer review?	Yes

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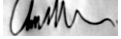
SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
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Stage of publication	

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the first author on this paper. I was responsible for designing the intervention and trial with advice from my supervisor and other co-authors. I drafted the manuscript. My co-authors supported this work in an advisory capacity and helped to edit the writing.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

Chapter transition notes

The intervention development paper (Chapter 3) described the intervention development process and the conceptual framework for the intervention. The next chapter (Chapter 4) is a research paper describing the MOTIF trial protocol. This paper, and the subsequent update, provides detail on the study design, intervention, study hypothesis, sample size calculation, outcome measures, effect measures and proposed statistical analysis methods.

MOBILE Technology for Improved Family Planning Services (MOTIF): study protocol for a randomised controlled trial

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4.1 Abstract

Background

Providing women with contraceptive methods following abortion is important to reduce repeat abortion rates, yet evidence for effective post-abortion family planning interventions are limited. This protocol outlines the evaluation of a mobile phone-based intervention using voice messages to support post-abortion family planning in Cambodia.

Methods/Design

A single blind randomised controlled trial of 500 participants. Clients aged 18 or over, attending for abortion at four Marie Stopes International clinics in Cambodia, owning a mobile phone and not wishing to have a child at the current time are randomised to the mobile phone-based intervention or control (standard care) with a 1:1 allocation ratio.

The intervention comprises a series of six automated voice messages to remind clients

about available family planning methods and provide a conduit for additional support. Clients can respond to message prompts to request a phone call from a counsellor, or alternatively to state they have no problems. Clients requesting to talk to a counsellor, or who do not respond to the message prompts, receive a call from a Marie Stopes International Cambodia counsellor who provides individualised advice and support regarding family planning. The duration of the intervention is three months. The control group receive existing standard of care without the additional mobile phone-based support.

We hypothesise that the intervention will remind clients about contraceptive methods available, identify problems with side effects early and provide support, and therefore increase use of post-abortion family planning, while reducing discontinuation and unsafe method switching. Participants are assessed at baseline and at four months. The primary outcome measure is use of an effective modern contraceptive method at four months post abortion. Secondary outcome measures include contraception use, pregnancy and repeat abortion over the four-month post-abortion period. Risk ratios will be used as the measure of effect of the intervention on the outcomes, and these will be estimated with 95% confidence intervals. All analyses will be based on the 'intention to treat' principle.

Discussion

This study will provide evidence on the effectiveness of a mobile phone-based intervention using voice messages to support contraception use in a population with limited literacy. Findings could be generalisable to similar populations in different settings.

Trial registration number

Keywords

Family planning, Post-abortion family planning, Contraception, mHealth, Cambodia

4.2 Background

Globally, an estimated 44 million pregnancies end in abortion each year, of which nearly half are unsafe, resulting in 47,000 maternal deaths.(204)(205) The vast majority of unsafe abortions occur in developing countries and account for one in eight maternal deaths. Around 80% of unintended pregnancies in developing countries occur among women who have an unmet need for modern family planning (FP).(204) Globally, if unmet need for FP were met, an estimated 75% of unsafe abortions could be avoided.(206)

The 2010 Cambodia Demographic Health Survey (CDHS) reported that 81% of women of reproductive age did not want any more children, or wished to wait at least two years for their next child, but only 35% were using a modern method of contraception.(77) Modern methods include condom, oral contraceptive (OC), injectable, implant, intra-uterine device (IUD) and permanent methods: vasectomy and sterilisation. The low use of contraception might contribute towards the high abortion rate in Cambodia, estimated at 50 per 1,000 women, well above the global average of 28 per 1,000.(80) Furthermore, among women who have had an abortion, 26% have had more than one. This highlights the need for more effective interventions to support clients with post-abortion family planning (PAFP).

There has been widespread uptake of mobile phones in low-income countries including Cambodia, with an estimated 19 million mobile subscriptions covering a population of approximately 14 million in 2012.(137) Marie Stopes International

Cambodia (MSIC) client exit surveys have estimated that over 80% of abortion clients own a mobile phone. The use of mobile phones to deliver healthcare ('mHealth') has the advantage over face- to-face healthcare delivery in that support can be delivered inexpensively wherever the person is located, when it is needed. This is of particular relevance in Cambodia where the women least likely to use a modern method of contraception are the rural poor.(77) Behaviour change techniques (BCTs) used in face-to-face interventions can be modified for delivery via mobile phones.(115)

Previous trials related to smoking cessation and HIV have reported objective evidence of altered health behaviour leading to improved health outcomes,(125)(123) yet there is more limited evidence related to the use of contraception.

Of the three previous trials in the USA to improve contraceptive use, Kirby (2010) reported no effect on contraception use with phone calls using motivational interviewing techniques,(174) and Hou (2010) reported no significant difference in mean numbers of missed pills with simple daily SMS reminders.(143) However, in a larger trial (n = 962), Castano (2010) reported that participants receiving daily educational text messages and pill reminders remained more likely to continue at six months (OR 1.41, 1.02-1.95).(142)

There is even less evidence for PAFP. No studies have formally reported mHealth PAFP interventions in low- income countries, although the 'm-assist: Mobile in Medical Abortion' trial has provisionally reported increased IUD uptake (21% vs. 13%) at seven weeks post abortion with a post-abortion SMS-based intervention in South Africa.(145)

Although these study results look promising, to date, the effect of mHealth interventions on PAFP, or on a wider range of contraceptive methods, has not been reliably established.

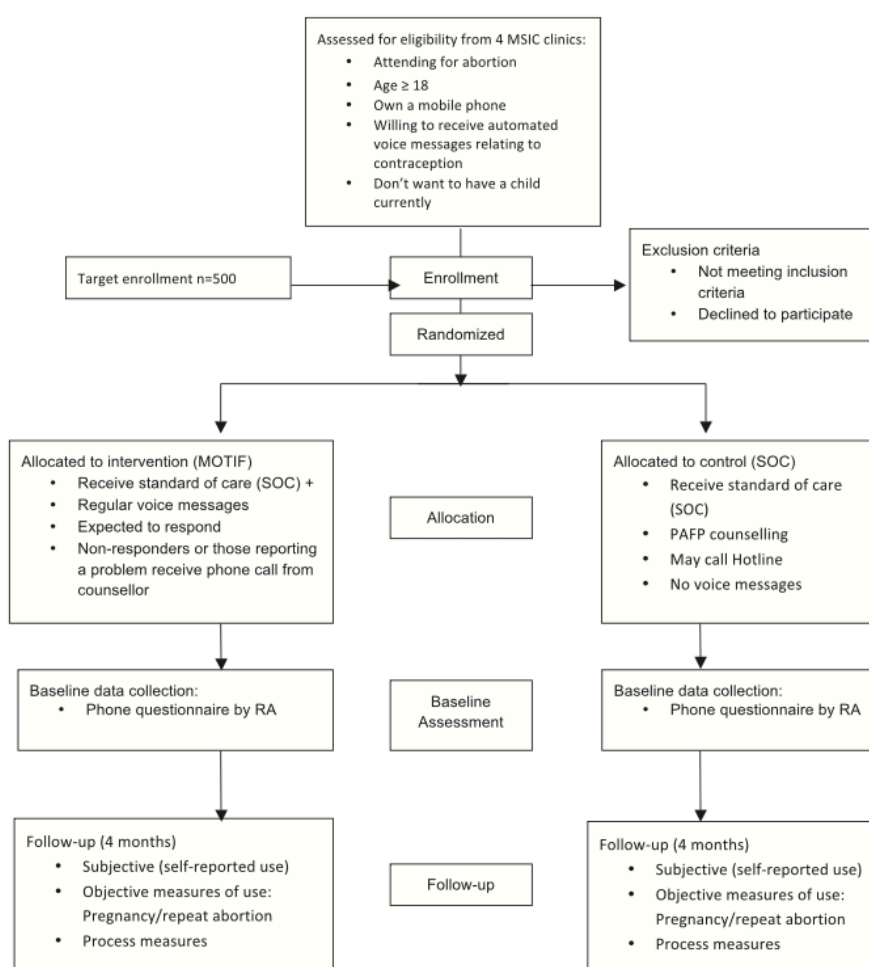
The MOBILE Technology for Improved Family Planning (MOTIF) project comprises the development, implementation and evaluation of a mobile phone-based intervention to support PAFP in Cambodia. This protocol outlines our proposed evaluation of the intervention developed.

4.3 Methods/Design

Study design

MOTIF is a multisite single-blind randomised controlled trial (RCT). Participants are randomised to the mobile phone-based intervention (voice messages and follow-up phone calls) or standard of care (SOC)/control (no additional mobile phone-based support) with a 1:1 allocation ratio (see Figure 31).

Figure 31: CONSORT diagram of study design



Setting and participants

Participants are recruited from four MSIC clinics; two serving predominantly urban populations around Phnom Penh City (Chbar Ambov and Takmao), and two based in provincial towns serving predominantly rural populations (Battambang and Siem Reap). Participants are eligible for the trial if they are attending for induced abortion, aged 18 years or over, own a mobile phone, do not want to have a child at the present time and are willing to receive simple voice messages from MSIC related to contraception. Clients are eligible regardless of whether they have decided to adopt PAFP after their abortion.

Potential trial participants are identified by service providers in the clinics who ask whether they would like to discuss participation in the trial with a research assistant (RA) at the end of the PAFP counselling session. RAs provide further information regarding the study. Given the high rates of illiteracy in Cambodia (literacy in rural areas was 69% according to the 2010 Cambodia DHS), the RA verbally explains the study by reading the Participants Information Sheet.⁽⁷⁷⁾ If the client wishes to participate, they sign, or thumbprint, two copies of the consent form. RAs collect baseline data from participants that are recruited. The RA provides a written list of all participants recruited, together with a unique trial identification (ID) number, to the counsellor delivering the intervention. The RA sends only the ID number together with the clinic status ('urban' or 'rural') of enrolled participants to a project statistician at the London School of Hygiene and Tropical Medicine (LSHTM) via email. Participants are stratified⁷ according to urban or rural clinic status and allocated to the intervention or control group using a remote computer-based randomisation programme.

⁷ It is incorrectly stated that participants were stratified where they were minimised. For further discussion on this issue see section 8.2

Allocation is therefore concealed from RAs working on the trial.

Intervention

The intervention was developed following a review of the literature, formative research including interviews and focus groups with abortion clients, and with input from clinicians and technology partners in Cambodia.(141) The intervention has a similar basis to the approach used by Lester (2010) in Kenya who hypothesised that a structured mobile phone protocol to keep in touch with patient could improve HIV medication adherence.(127) Detailed description of the intervention development will be reported elsewhere.

The MOTIF conceptual framework is based on existing literature on the determinants of contraceptive use, links between contraceptive use and fertility, and effective adherence interventions (See Chapter 3, Figure 30).(51)(207)

The MOTIF intervention comprises a series of automated voice messages to participants' mobile phones over the three-month period following their abortion, at times of their preference. Clients receive the first message within one week of receiving abortion services and then every two weeks, with a total of six messages. The messages are designed to remind clients about FP methods available to them and provide a conduit for additional support. A typical message, recorded in the Cambodian (Khmer) language, is as follows:

'Hello, this is a voice message from a Marie Stopes counsellor. I hope you are doing fine. Contraceptive methods are an effective and safe way to prevent unplanned pregnancy. I am waiting to provide free and confidential contraceptive support to you. Press 1 if you would like me to call you back to discuss contraception. Press 2 if you are comfortable with using contraception and you do not need me to call you back this time. Press 3 if you would prefer not to receive any messages again'

Clients who indicate they would like to talk to a counsellor, or who do not respond to

the message prompts, receive a call from an MSIC counsellor. The counsellors provide individualised information on contraceptive methods and advice if the client is experiencing side effects from contraception. Clients are advised to use condoms as dual protection from HIV and sexually transmitted infections as appropriate. Follow-up calls to clients are made during preferred times indicated by the client on her registration form. Clients in the intervention arm are also able to call the MOTIF service at any time to request to speak with a counsellor. Clients who opt to receive the OC or injectable can opt in to receive additional reminder messages appropriate to their method (that is, to start a new packet of pills or when to receive a new injection). The sixth and final voice message provides similar information to the first five, but also reminds the client that this will be the last message they will receive.

The MOTIF intervention is delivered by trained counsellors at the MSIC head office in Phnom Penh. Voice messages are scheduled and sent using the open-source software programme 'Verboice', developed by InSTEDD (instedd.org). Verboice has functionality with all the mobile phone network operators. MSIC incurs the cost of outgoing communication from the provider to client, and clients incur any costs calling into the service (the cost of a local call). The counsellor records information on the voice messages sent, responses to messages and outcomes of follow-up phone calls.

Control

Participants in the control group receive the current existing SOC, but not the voice messages or follow-up phone calls. Existing SOC includes: face-to-face post-abortion counselling; a clinic follow-up appointment at one or two weeks; the clinic phone number and hotline phone number: a toll-free help line for clients staffed by trained counsellors at the MSIC head office.

Objectives

The objective of the study is to test whether additional regular, structured, interactive mobile phone-based support improves use of PAFP. We hypothesise that the intervention will remind clients about contraceptive methods available, identify problems with side effects early and provide appropriate support, and will boost motivation to use PAFP, while reducing discontinuation and unsafe method switching. Therefore we hypothesise that the intervention will increase use of PAFP compared to clients receiving SOC (control).

Outcome measures

Baseline characteristics of study participants in both the intervention and control groups will be compared with those of the general clinic population. We will assess recruitment rates, numbers assessed for eligibility compared with numbers enrolled, and completeness of follow-up.

Primary outcomes

The primary outcome measure is use of an effective modern contraceptive method at four months post abortion. We define effective modern methods to be those associated with <10% 12-month pregnancy rates, as commonly used: OC, injectable, implant, IUD, or permanent methods.(6) At four months, all trial participants will be contacted by phone to collect self-report data on all outcomes.

Participants are considered 'users' or 'non-users' of effective modern contraception according to method: implant (participant currently has a sub-dermal implant); IUD (participant currently has IUD inserted); injectable (client has received injection within the previous three months); permanent method (client, or husband/partner has had sterilisation or vasectomy procedure); OC (participant reports having taken pill within

24 hours of interview or, if on 7-day break, took the last pill according to instructions).

Although self-reported data on contraception use are considered less reliable, and prone to social desirability bias, it is the standard approach for contraception research and it will provide data that are comparable to previous studies.(189)(188)

In order to assess the validity of self-reported data, a reliability study based on approximately 50 participants recruited from the clinics near Phnom Penh will be conducted. Participants who have already provided self-report follow-up who were recruited from Chbar Ambov and Takmao clinics will be contacted in sequential order, and requested to attend the clinic of their choice for face-to-face follow-up for objective measurement on all contraception outcomes. This will include urine pregnancy testing and measures of contraceptive adherence (presence of sub-dermal implant, or documentary evidence of insertion, clinical examination to identify coil threads or documentary evidence of insertion, documentary evidence of injection within the previous three months, documentary evidence of sterilisation, pill counts defined as >90% of pills taken since last prescription dispensed).

Secondary outcomes

Secondary outcome measures include self-reported pregnancy, repeat abortion, contraception use over the four-month post-abortion period (to estimate point prevalence of contraception use at any given time and contraceptive discontinuation rates), and involvement in any domestic abuse or road traffic accidents (RTA). RTAs are rare, but the only adverse health effect of cell phone use for which there is evidence.(164)

Sample size

Analysis of 2011 MSIC clinic data indicated that the proportion of clients using an

effective contraceptive method at two weeks post abortion was 44%. The trial will involve the same population so it is reasonable to assume similar PAFP use in the control group. Aggregate demographic and health, and Cambodian, survey data indicate that around 30% of women using hormonal methods and 10% using the coil discontinue within one year, many before three months of use.(87)(88) Contraception use, repeat pregnancy or abortion rates in MSIC clinics after two weeks are not known. Based on aggregate data, we anticipate 20% discontinuation from two-week acceptance, and therefore 35% of clients will be using an effective method at four months post abortion.

The trial has been designed to detect an increase of 13% in contraceptive use at four months as results from previous mHealth HIV adherence and face-to-face contraception adherence interventions suggest that it is reasonable to anticipate an effect of this size. Canto De Cetina (2001) reported a 26% decrease in injectable discontinuation at one year with an intervention providing structured face-to-face counselling versus routine information.(208) Lester (2010) reported a 12% increase in self-reported adherence among those receiving the mHealth intervention compared to routine care.(127)

In the four trial clinics there were over 1,500 abortions during a three-month period in 2011, therefore even accounting for refusals and reduced recruitment due to clinic staff time pressure, we believe it will be possible to recruit 500 participants over a three-month period. A trial of 500 has 80% power to detect a difference in contraceptive use of 35% vs. 48% (that is, relative risk 1.4) at the 5% significance level (that is, $P < 0.05$). It is not possible to adequately power the study for the rare secondary outcomes of repeat pregnancy and abortion.

Data collection

At present, around 50% of clients do not return to the clinic for any reason after attending for abortion, therefore all trial participants will be actively followed up by a RA to assess outcome measures. Data collection tools include baseline and follow-up questionnaires: designed in English, translated to Khmer and administered by local RAs fluent in Khmer. The baseline questionnaire contains questions to collect information on contact details, demographics, reproductive history and plans, circumstances of current abortion and mobile phone use.

The follow-up questionnaire contains questions to collect information on changes in demographics, current contraception use, contraception use over the four-month post-abortion period, and any reported domestic abuse or RTA that could have resulted from mobile phone use. In addition to self-reported measures, clients that attend the clinic for face-to-face follow-up will be offered urine pregnancy testing and objective assessment of contraceptive use by a clinically trained RA.

The follow-up questionnaire assesses births, pregnancies, contraceptive use and discontinuation over a period of time using a similar format to that used in the CDHS.

Analysis plan

Analysis of primary and secondary outcomes

We will report the trial according to the CONSORT standards for reporting RCTs. This is a behavioural intervention unlikely to produce adverse effects, so analysis will be undertaken once the four-month follow-up has been completed.

Intention-to-treat (ITT) principles will be used for primary outcome analysis; therefore all participants will be analysed according to the arm to which they were randomised.

During ITT analysis, participants lost to follow-up, resulting in missing contraceptive

use outcome data at four months, will be considered non-users.

Sensitivity and per-protocol analysis

We will conduct an additional sensitivity analysis including only participants who completed the four-month follow-up. Per-protocol analysis will be undertaken to assess the impact of the intervention among those who actively participated in the intervention. Participants who respond to three or more of the six voice messages over the intervention period will be considered highly protocol adherent. Participants who respond to between one and three messages will be considered less protocol adherent. Those who never responded to a voice message will be considered as never responding and not included in the sensitivity analysis.

Sub-group analysis

We will undertake exploratory sub-group analyses to assess evidence for whether the effect of the intervention varies according to age, urban versus rural residence, level of education, and socioeconomic status. If statistically significant overall heterogeneity is identified then relative risks and 99% confidence intervals will be estimated.

Statistical methods

For the primary outcome and secondary outcomes we will estimate risk ratios with 95% confidence intervals. We will calculate the sensitivity and specificity of self-reported contraception use as compared to objective measurement, and comment on any limitations of the respective methods of data collection. We will undertake Kaplan-Meier survival analysis to compare contraceptive discontinuation rates. Analysis will be conducted using STATA (Table 15).(209)

Table 15: Outcome measures and methods of analysis

Outcome	Outcome measure	Method of analysis
1. Primary		
Use of an effective modern method of contraception at 4 months	Self-report (binary) Objective ^a (binary)	Chi-squared test
2. Secondary		
Pregnancy	Self-report (binary) (0, 1 or more) Urine pregnancy test ^a (binary)	Chi-squared test
Repeat abortion	Self-report (binary) (0, 1 or more)	Chi-squared test
Effective modern contraception use over 4-month period	Self-report (binary) (<80%, >80%)	Chi-squared test
Contraceptive discontinuation	Discontinuation after starting contraceptive method (time to event)	Kaplan-Meier survival analysis
Involvement in road traffic accident	Self-report (binary)	Chi-squared test
Domestic abuse	Self-report (binary)	Chi-squared test
3. Sensitivity and per-protocol analysis		
Participants that completed follow-up	All outcomes	Chi-squared/T-test/logistic and linear regression
Clustering among participants from one clinic		
Per-protocol analysis		
4. Sub-group analysis	All outcomes	
Age		
Urban versus rural residence		Logistic/linear regression
Level of education		
Socioeconomic status		

Follow-up at 4 months for all participants will comprise a telephone interview conducted by a research assistant.

^aApproximately 50 participants from one clinic will be requested to attend for face-to-face follow-up for objective measurement of contraceptive outcomes.

Additional analysis

Data arising from the intervention

We will provide a descriptive analysis of data generated by the intervention to include number of voice message and phone interactions, response to voice messages, and time spent on phone calls, to facilitate description of problems and issues.

Additionally, at the end of the trial, the costs of the intervention (training, human resources, phone costs and so on) will be estimated.

Qualitative interviews

We will conduct around 15 to 20 qualitative interviews with participants who received the intervention. Participants for interview will be selected purposively to include those who did or did not appear to respond to the intervention: both users and non-users of contraception. The interviews will explore participants' experience of the intervention, aiming to identify active components of the intervention, and seek

recommendations for improvements. Interviews will be recorded and transcribed and a simple thematic analysis undertaken. We will use the findings to inform any adjustments to the intervention after the trial.

Analysis of long-term follow-up at 12 and 24 months

The main purpose of taking contraception is to avoid unwanted pregnancy. While it is likely that few participants will report repeat pregnancy and/or abortion at four months, differences in these important outcomes may become apparent over a longer period of time. During trial recruitment, participants are given the option to consent for additional follow-up of primary and secondary outcomes at 12 and 24 months. This additional follow-up will be dependent on receiving additional funding and participants will be informed whether this additional follow-up is likely to occur at the end of the study.

Ethics

The trial is being conducted in accordance with the principles of Good Clinical Practice.⁽¹⁵¹⁾ Ethical approval for the study protocol was granted by the LSHTM ethics committee, the MSI ethics committee and the Cambodia Human Research Ethics Committee. The MOTIF trial is registered with ClinicalTrials.gov, number: NCT01823861.⁽¹⁵²⁾

All participants provide written consent before enrolling in the trial or commencing the follow-up interview. All client records, written, recorded and transcribed data are stored securely. No names of participants (or others mentioned) or locations will be used in the analysis or report writing. Confidentiality will be maintained by assigning coded identifiers to participant names (with a master list stored separately).

Participants are able to withdraw from the study at any point. Any participants raising

a personal sexual issue or consequences arising from other people listening to voice messages (for example, an argument or violence) will be linked into appropriate services, either at MSIC, or other local organisations.

Participants are reimbursed to compensate for expenses related to face-to-face clinic follow-up, but not for participation in the trial. Participants are not provided with mobile phones or airtime.

4.4 Discussion

The MOTIF trial will provide rigorous evaluation of a novel mobile phone-based intervention to support PAFP; and will contribute towards the evidence base on mHealth interventions for contraception. The MOTIF trial is unique in a number of ways. First, to our knowledge this is the first RCT of a mobile phone-based intervention using voice messages to support PAFP. Given the paucity of evidence for effective interventions for PAFP in low-income settings, further research in this area is important. The MOTIF trial has been carefully designed to minimise bias and collect information on important health outcomes, while taking into account the sensitivities of undertaking research with post-abortion clients. Due to the nature of the intervention, the trial can only be single-blind and study participants will be aware of intervention allocation. However, allocation will be concealed to clinicians and RAs working on the trial. Second, it examines the interventions effect on both users and non-users of contraception, on a range of contraceptive methods over a period of time. Previous mHealth contraception interventions have often been focused on one particular method, often the OC. In addition to the OC, the MOTIF intervention will

promote long-acting⁸ methods which are associated with less user-failure. We believe that given high rates of dissatisfaction with methods, leading to discontinuation, interventions that promote safe method switching, as well as support for clients experiencing side effects, will lead to increased contraceptive use overall and reduced unintended pregnancy. Third, to our knowledge, this is one of the first RCTs of a mobile phone-based intervention to support contraception use in a low-income setting. To date, most RCTs of mHealth interventions to support contraception use have been conducted in the USA, the exception being the mAssist trial in South Africa.⁽¹⁴⁵⁾ Other mobile phone-based contraception initiatives that have been launched and scaled up in low-income settings include Mobile for Reproductive Health (m4RH), Cycle Tel, Mobile Alliance for Maternal Action (MAMA), each with different approaches to the intervention and evaluation, but limited evidence of health impacts to date.⁽¹⁴⁶⁾⁽¹⁴⁹⁾⁽¹⁴⁷⁾

No single trial or initiative will answer the question of whether mHealth interventions are effective in supporting contraception use and we also recognise that mHealth is a dynamic area, with rapid changes in both technology and the techno-literacy of populations; hence, what works or does not work now may not hold true in a few years' time. The MOTIF trial will provide evidence on the effectiveness of voice messages to support contraception use in populations with limited literacy, and findings could be generalisable to similar populations in different settings. Therefore, in addition to publishing the findings from our statistical analysis we intend to report on our analysis of why the intervention did or did not work, what BCTs appear to be the 'active components' of the intervention, technological successes and challenges,

⁸ Intrauterine device, implant or permanent method

and cost and resource implications for scale-up of the intervention. This should ensure that the learning from this study will be of the greatest possible value to other organisations or researchers seeking to develop similar interventions.

Trial status

Recruiting.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CS and CF designed the intervention and the trial. CS drafted the manuscript. UV and LS assisted with formative research to develop the intervention. PE advised on the statistical analysis plan and helped to draft the manuscript. TN, JG, KK and TR participated in the design of the study. CF, TN, JG, KK and TR helped to draft the manuscript. All authors read and approved the final manuscript.

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Funding for the MOTIF study (£146,736) was obtained through the Marie Stopes International Innovation Fund award over a 15-month period commencing October 2012. We would like to thank the many clients who contributed towards the development of the intervention. We would also like to thank the following organisations and individuals: InSTEDD, Open Institute, BBC Media Action, Stefanie Wallach (MSIC), Melissa Cockcroft (MSIC), Seaklong Keam (MSIC), Nicky Jurgens (MSIC), Thou Chum (MSIC), Isolde Birdthistle (LSHTM), Susannah Mayhew (LSHTM), John Cleland (Professor of Demography, LSHTM), Anna Glasier (Honorary Professor, University of Edinburgh and Department of Public Health and Policy, LSHTM), Ona

McCarthy (LSHTM), Jerker Liljestrand (URC, Cambodia), Deborah Constant (University of Cape Town) and Ali Flaming (Occidental College).

RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	Trials journal. Citation: Smith et al.: MOBILE Technology for Improved Family Planning: update to randomised controlled trial protocol. Trials 2014 15:440.		
When was the work published?	Received: 4 September 2014 Accepted: 31 October 2014 Published: 12 November 2014		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Yes. It is Open Access and the article is distributed under the terms of the Creative Commons Attribution License which permits unrestricted use, distribution and reproduction in any medium provided the work is properly cited. The work is not being included in its published format (it has been converted to Word format, tables and figures have been re-created as per the rest of the thesis). The journal has given permission for this work to be included in the thesis (see Appendix 5)	Was the work subject to academic peer review?	Yes

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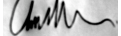
SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	

Stage of publication	
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the first author on this paper. I was responsible for drafting this manuscript with input from my supervisor, other co-authors and PhD upgrading examiners Richard Hayes and Isolde Birdthistle.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

4.5 MOBILE Technology for Improved Family Planning: update to randomised controlled trial protocol

Chris Smith¹, Thoai D Ngo², Phil Edwards¹, Caroline Free¹

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4.5.1 Abstract

Background

This update outlines changes to the MOBILE Technology for Improved Family Planning study statistical analysis plan and plans for long-term follow-up. These changes result from obtaining additional funding and the decision to restrict the primary analysis to participants with available follow-up data. The changes were agreed prior to finalising the statistical analysis plan and sealing the dataset.

Methods/design

The primary analysis will now be restricted to subjects with data on the primary outcome at four-month follow-up. The extreme-case scenario, where all those lost to follow-up are counted as non-adherent, will be used in a sensitivity analysis. In addition to the secondary outcomes outlined in the protocol, we will assess the effect of the intervention on long-acting contraception (implant, intra-uterine device and permanent methods).

To assess the long-term effect of the intervention, we plan to conduct additional 12-month follow-up by telephone self-report for all the primary and secondary outcomes used at four months. All participants provided informed consent for this additional follow-up when recruited to the trial. Outcome measures and analysis at 12 months

will be similar to those at the four-month follow-up. The primary outcomes of the trial will be the use of an effective modern contraceptive method at four months and at 12 months post-abortion. Secondary outcomes will include long-acting contraception use, self-reported pregnancy, repeat abortion and contraception use over the 12-month post-abortion period.

Discussion

Restricting the primary analysis to those with follow-up data is the standard approach for trial analysis and will facilitate comparison with other trials of interventions designed to increase contraception uptake or use. Undertaking 12-month trial follow-up will allow us to evaluate the long-term effect of the intervention.

Trial registration

ClinicalTrials.gov NCT01823861.

4.5.2 Update

Background

This update outlines changes to the MOBILE Technology for Improved Family Planning (MOTIF) study statistical analysis plan and plans for long-term follow-up. These changes, subsequent to the publication of the protocol in *Trials*,⁽¹⁶⁷⁾ result from discussions within the research team, recommendations from one author's (CS) PhD examiners, and procurement of additional funding to conduct further follow-up. The changes were agreed and we informed *Trials* on 12 June 2014 prior to finalising the statistical analysis plan and sealing the dataset.

Changes to four-month analysis

The primary analysis will be restricted to participants with available follow-up data.

This is a more common approach to trial analysis and is standard in trials of interventions designed to increase contraception use.⁽¹⁴³⁾⁽¹⁴²⁾⁽¹⁴⁴⁾ This change will therefore facilitate comparison of our results with other studies. The primary outcome remains the same: use of an effective modern method of contraception at four months post-abortion. For the primary analysis, we originally planned to consider all participants lost to follow-up as non-users of contraception. This is clearly an extreme-case scenario and is likely to underestimate contraceptive rates, as it is unlikely that all subjects lost to follow-up will be non-users. We now consider that this would be more appropriate for a sensitivity analysis. While the subset of subjects with follow-up data might not be representative of all subjects, comparison across arms should provide an internally valid comparison, providing follow-up rates are similar in the intervention and control arms.

In addition to the secondary outcomes outlined in the protocol, we will assess the effect of the intervention on long-acting contraception. Marie Stopes International Cambodia considers implant, intra-uterine device and permanent methods to be long-acting contraception. We anticipate that this additional secondary analysis will be of value to family planning service providers. The researchers conducting the data analysis will be blind to treatment allocation. A second independent researcher will check the analyses.

Long-term trial follow-up

At recruitment, participants were given the option to consent for additional self-report follow-up of primary and secondary outcomes at 12 and 24 months, subject to the

trial's obtaining additional funding. All 500 trial participants provided consent for this potential additional follow-up. Subsequently CS obtained a Medical Research Council Population Scientist Fellowship, which included some funds for long-term MOTIF trial follow-up.

We obtained self-report follow-up data on 86.2% of participants at four months. Six participants withdrew from the study. This follow-up was conducted by two research assistants over a five-month period.

To assess the long-term effect of the intervention, we plan to conduct 12-month trial follow-up on the remaining 492 trial participants, commencing July 2014. The follow-up questionnaire will be similar to that used at four months. We will collect information on current contraceptive use, repeat pregnancy or abortion, and contraception use over the 12-month post-abortion period. In addition, we will ask participants using contraception where they obtained it. We anticipate that it will take several months to conduct 12-month follow-up. Having achieved 86.2% follow-up at four months, we anticipate increased attrition at subsequent follow-up. Owing to limited resources, we will not complete follow-up at 24 months.

Outcome measures and analysis will be similar to those at the four-month follow-up. The primary outcome at the 12-month follow-up will be use of an effective modern contraceptive method at *12-months* post-abortion. This will be considered a second primary outcome, in addition to effective modern contraceptive use at four months. Secondary outcomes include long-acting contraception use, self-reported pregnancy, repeat abortion, and contraception use over the *12-month* post-abortion period (to estimate the point prevalence of contraception use at any given time and of contraceptive discontinuation rates).

For the primary outcomes and for secondary outcomes with binary outcome measures we will estimate risk ratios with 95% confidence intervals and give a two-sided *P* value for statistical significance using the chi-squared test. We will perform Kaplan-Meier survival analysis to assess contraceptive discontinuation rates.

We will perform sub-group and sensitivity analysis as per the four-month analysis. For sub-group analysis, we will assess whether the effect of the intervention varies according to age, urban versus rural residence, level of education and socioeconomic status. We will use the chi-squared test for heterogeneity at a 5% level of significance. If statistically significant overall heterogeneity is identified, relative risks and 99% confidence intervals will be estimated. Sensitivity analysis will include counting those lost to follow-up as non-users, per-protocol analysis, and analysis of clustering among participants from each clinic, as for the four-month follow-up.

Ethics

Ethical approval for this additional follow-up has been granted by the London School of Hygiene and Tropical Medicine ethics committee (reference number 6378–01), the Marie Stopes International ethics committee (reference number 002-13-Am14), and the Cambodia Human Research ethics committee (reference number 0193 NECHR).

Conclusion

Restricting the primary analysis to those with follow-up data is the standard approach for trial analysis and will facilitate comparison with other trials of interventions designed to increase contraception uptake or use. Undertaking 12-month trial follow-up will allow us to evaluate the long-term effect of the intervention.

Abbreviation

MOTIF: MOBILE Technology for Improved Family Planning.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CS and CF designed the intervention and the trial. PE and TDN participated in discussions and agreed the changes outlined in this update. CS drafted the manuscript. CF helped to draft the manuscript. All authors read and approved the final manuscript.

Authors' information

CS is a Clinical Research Fellow in the Department of Population Health at the London School of Hygiene and Tropical Medicine and a PhD candidate on the topic of mobile phone-based interventions to improve use of contraception. TDN is Head of Research at Marie Stopes International. PE is a Senior Lecturer in Statistics in the Department of Population Health at London School of Hygiene and Tropical Medicine. CF is a Senior Lecturer in Epidemiology in the Department of Population Health at London School of Hygiene and Tropical Medicine.

Acknowledgements

Funding for the long-term follow-up and data analysis has been provided by the UK Medical Research Council. We would like to thank Richard Hayes, Isolde Birdthistle, Rebecca Sear, Emma Slaymaker and Uk Vannak for their input

5. Effect of a mobile phone-based intervention on post-abortion contraception: a randomized controlled trial in Cambodia

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SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	Bulletin of the World Health Organization. Citation: Smith C, Ngo TD, Gold J, Edwards P, Vannak U, Machiyama K, et al. Effect of a mobile phone-based intervention on post-abortion contraception: a randomized controlled trial in Cambodia. Bull World Health Organ [Internet]. 2015; Available from: http://www.who.int/bulletin/online_first/en/		
When was the work published?	Submitted: 18 June 2015 – Revised version received: 3 September 2015 – Accepted: 16 September 2015 – Published online: 15 October 2015		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	This article is available under the Creative Commons Attribution 3.0 IGO licence which permits unrestricted use, distribution and reproduction in any medium provided the original work is properly cited. The work is not being included in its published format (it has been converted to Word format, tables and figures have been re-created as per the rest of the thesis). The journal has given permission for this work to be included in the thesis (see Appendix 5)	Was the work subject to academic peer review?	Yes

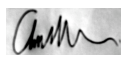
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Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the first author on this paper. I was responsible for conducting the statistical analysis and drafting the manuscript. My co-authors supported this work in an advisory capacity, assisted with statistical analysis and helped to edit the writing.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

Chapter transition notes

The previous chapter (Chapter 4) described the trial protocol. This chapter (Chapter 5) is a research paper that presents the results of the MOTIF randomised controlled trial and includes data on baseline characteristics of participants, primary and secondary outcomes collected at four and 12-month follow up, as well as subgroup and discontinuation figures for the 12-month follow up data.

In addition to the published trial paper, this chapter contains three additional analyses. This includes pre-specified analyses that that could not be included in the main trial paper due to word count limitations such as additional discontinuation figures (Section 5.6), an analysis assessing the validity and reliability of self-report data on contraception use collected in the trial (Section 5.7) and sensitivity analyses (Section 5.8).

In addition I have undertaken some exploratory analyses not originally planned for the PhD to provide additional insights into the mechanism of action of the intervention, explore follow up approaches and methods of dealing with missing data. These include an analysis of dynamics of contraception use over the post-abortion period (Section 5.6), an overview of approaches to measuring adherence to effective contraceptive methods (Section 5.7), and an analysis assessing factors associated with loss to follow-up in the trial and comparing how the result might have varied using different analysis methods such as multiple imputation (Section 5.8). Whilst I conceived the idea for the paper exploring factors associated with loss to follow-up and conducted the logistic regression analysis, a statistician (Christopher Jarvis) coded the multiple imputation and added the follow text to the paper: *“Logistic regression with predictor variables age group, socioeconomic status, and education was used for univariate imputation of the outcome. Multiple imputation was conducted separately for the outcome at 4 and 12 months with 100 imputed datasets created for each outcome respectively”*.

Currently the additional analyses have not been prepared for publication, but it is possible that Sections 5.7 and 5.8 might be prepared and submitted for publication in the future.

Effect of a mobile phone-based intervention on post-abortion contraception: a randomized controlled trial in Cambodia

Chris Smith,^a Thoai D Ngo,^b Judy Gold,^c Phil Edwards,^a Uk Vannak,^d Ly Sokhey,^d Kazuyo Machiyama,^a Emma Slaymaker,^a Ruby Warnock,^d Ona McCarthy^a & Caroline Free^a

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5.1 Abstract

Objective

To assess the effect of a mobile phone-based intervention (mHealth) on post-abortion contraception use by women in Cambodia.

Methods

The Mobile Technology for Improved Family Planning (MOTIF) study involved women who sought safe abortion services at four Marie Stopes International clinics in Cambodia. We randomly allocated 249 women to a mobile phone-based intervention, which comprised six automated, interactive voice messages with counsellor phone support, as required, whereas 251 women were allocated to a control group receiving standard care. The primary outcome was the self-reported use of an effective contraceptive method, four and 12 months after an abortion.

Findings

Data on effective contraceptive use were available for 431 (86%) participants at 4 months and 328 (66%) at 12 months. Significantly more women in the intervention

than the control group reported effective contraception use at four months (64% versus 46%, respectively; relative risk, RR: 1.39; 95% confidence interval, CI: 1.17–1.66) but not at 12 months (50% versus 43%, respectively; RR: 1.16; 95% CI: 0.92–1.47). However, significantly more women in the intervention group reported using a long-acting⁹ contraceptive method at both follow-up times. There was no significant difference between the groups in repeat pregnancies or abortions at four or 12 months.

Conclusion

Adding a mobile phone-based intervention to abortion care services in Cambodia had a short-term effect on the overall use of any effective contraception, while the use of long-acting contraceptive methods lasted throughout the study period.

5.2 Introduction

Unmet need for contraception can result in unintended pregnancy and avoidable maternal and infant deaths.(1) It has been estimated that, if the need for modern contraception methods were met, 52 million unintended pregnancies, 24 million abortions (over half of which would be unsafe) and 70 000 maternal deaths would be prevented among women in low-income countries each year. Nevertheless, 225 million women in these countries had an unmet need for contraception in 2014.(155) Women who seek an abortion are likely to have an unmet need for contraception and the time after an abortion provides a key opportunity to offer family planning services.(29) Typically, women are counselled on family planning before discharge from clinical care after seeking abortion services.(210) However, quality of service provision varies and evidence on the ability of enhanced counselling interventions to

⁹ Intrauterine device, implant or permanent method

improve post-abortion family planning is inconclusive.(93)(94) In Cambodia, despite the total fertility rate declining from 3.4 births per woman in 2005 to 3.0 births per woman in 2010, there remains an unmet need for contraception: in 2010, 81% of women of reproductive age reported wanting to delay their next child or to have no more children but only 35% reported currently using a modern contraceptive method.(77) The abortion rate in the country was estimated to be 50 per 1000 women, compared to a global average of 28 per 1000,(80) and 26% of women who sought abortion services had had more than one abortion.(77) Interventions delivered by mobile phone could help increase the uptake and continuation of post-abortion family planning in countries like Cambodia where over 90% of the 2066 women surveyed report owning a mobile phone.(211) Health interventions delivered by mobile phone can utilize different approaches (e.g. text messages, voice messages or smartphone applications) depending on the literacy of the population and the devices available.(116) Compared with face-to-face interventions, mobile phone-based interventions have the advantage that they can provide interactive, personalized support inexpensively wherever the person is located and whenever needed. Our research suggested that women in Cambodia often found it difficult to make decisions about contraception at the time of seeking abortion services; they needed more time, to wait for their health to improve or to speak with family or friends.(212) Hence, in this setting, where 80% of the population live in a rural area and geographical distances can restrict access to services, mobile phone-based interventions may provide an effective method for maintaining communication with clients after they leave the clinic.(77)(115) Interventions delivered by mobile phone have been shown to be effective in other health areas, such as smoking cessation and adherence to

treatment for human immunodeficiency virus infection.(125)(123) However, the evidence from three small trials in which a mobile phone-based intervention was used to increase contraceptive use has been inconclusive.(142)(143)(144) The objective of our study was to evaluate the effectiveness of a mobile phone-based intervention designed to support post-abortion contraception in Cambodia. The specific aims were to increase the uptake of effective contraceptive methods and to reduce contraceptive discontinuation.

5.3 Methods

Our study - the Mobile Technology for Improved Family Planning (MOTIF) study - was a single-blind, randomized trial of a personalized, mobile phone-based intervention designed to support post-abortion family planning. The protocol was published in 2013.(167)(213) The trial was undertaken at four Marie Stopes International clinics in Cambodia that provided safe abortion services: two served peri-urban populations around Phnom Penh city (i.e. Chbar Ambov and Takmao) and two served provincial towns with a predominantly rural population (i.e. Battambang and Siem Reap). All women older than 17 years who sought an induced abortion were eligible for inclusion if they had a mobile phone primarily for their own use, reported not wanting to become pregnant and were willing to receive automated voice messages about contraception. Research assistants interviewed women after they had received post-abortion family planning counselling at the clinic to assess their eligibility for the study and to collect baseline data. Participants provided consent by written signature or thumbprint. Ethical approval was obtained from ethics committees at the London School of Hygiene & Tropical Medicine and Marie Stopes International and the Cambodia Human Research ethics committee. The trial was registered through

ClinicalTrials.gov with the identifier NCT01823861. Research assistants provided a written list of participants, each with a unique identification number, to counsellors delivering the intervention. The project statistician at the London School of Hygiene & Tropical Medicine, London, United Kingdom of Great Britain and Northern Ireland, received only the identification number and the urban or rural clinic classification of each participant. The statistician allocated participants to the intervention or control group on a 1:1 basis using Minim (<https://www-users.york.ac.uk/~mb55/guide/minim.htm>), a computer randomization program that stratified¹⁰ them according to whether their clinic was urban or rural. The identification numbers of participants allocated to the intervention were sent to the counsellors between 1 May and 27 September 2013. Researchers who undertook data collection and analysis were blinded to the treatment allocation.

All participants received existing standard care, which included post-abortion family planning counselling at the clinic in accordance with national guidelines, the offer of a follow-up appointment at the clinic and details of the clinic's phone number and of a hotline number operated by counsellors at Marie Stopes International Cambodia.

Those allocated to the intervention, which lasted three months, also received six automated, interactive voice messages and were provided with phone support from a counsellor depending on their responses to the messages (Table 16). Participants who chose to receive oral or injectable contraceptives could opt for additional reminder phone messages appropriate to their method. Participants in the control group did not receive voice messages.

¹⁰ It is incorrectly stated that participants were stratified where they were minimised. For further discussion on this issue see section 8.2

The intervention was delivered by trained counsellors at Marie Stopes International Cambodia. Voice messages were scheduled and sent using the open-source software program Verboice (InSTEDD, Palo Alto, United States of America). The cost of outgoing communications from the provider to the participant was met by Marie Stopes International Cambodia and the cost of calling into the service (i.e. a local call) was incurred by participants.

Table 16: The mobile phone-based intervention

The conceptual framework for the intervention used in the MOBILE Technology for Improved Family Planning (MOTIF) study was based on literature reports on the determinants of contraceptive use and on links between contraceptive use and fertility.¹⁸ The intervention comprised six automated voice messages sent to participants' mobile phones, at the time of their preference, during the 3 months following an abortion. Participants received the first message within 1 week of using abortion services and every 2 weeks thereafter. The message, recorded in the Khmer language, was as follows: Hello, this is a voice message from a Marie Stopes counsellor. I hope you are doing fine. Contraceptive methods are an effective and safe way to prevent an unplanned pregnancy. I am waiting to provide free and confidential contraceptive support to you. Press 1 if you would like me to call you back to discuss contraception. Press 2 if you are comfortable with using contraception and you do not need me to call you back this time. Press 3 if you would prefer not to receive any more messages. Participants who pressed 1 or who did not respond received a phone call from a counsellor. The phone calls were intended to encourage contraceptive use by increasing the client's capability of using contraception by: (i) providing individualized information on a range of contraceptive methods; (ii) increasing the participant's opportunity to use contraception, for example, by informing her where she could access specific methods near her residence; and (iii) increasing motivation by reinforcing knowledge of the benefits of contraception. At the participant's request, the counsellor would also discuss contraception with her husband or partner. Participants were also able to call the service and ask to speak to a counsellor. Those who chose to receive an oral or injectable contraceptive could opt to receive additional reminder messages appropriate to their method (e.g. on when to start a new packet of pills or when to receive a new injection). The sixth and final voice message was similar but also reminded the participant that this was the last message they would receive. The intervention was delivered by trained counsellors at Marie Stopes International Cambodia. Voice messages were scheduled and sent using the open-source software program Verboice (InSTEDD, Palo Alto, United

States of America). The cost of outgoing communications from the provider to the participant was met by Marie Stopes International Cambodia and the cost of calling into the service (i.e. a local call) was incurred by participants.

The formative research carried out to develop the intervention will be reported elsewhere. The primary outcome was the self-reported use of an effective contraception method, four and 12 months after an abortion. Effective methods were defined as those that have been associated with a 12-month pregnancy rate below 10% (a common criterion in developing countries), such as oral contraceptives, three-monthly contraceptive injections, subdermal implants, intrauterine devices and permanent methods, such as sterilization or vasectomy.⁽⁷⁾⁽⁶⁾ A participant was regarded as using an effective method if she reported that she: (i) currently had a contraceptive implant or an intrauterine device in place; (ii) had received a contraceptive injection within the previous three months; (iii) had undergone sterilization or her husband or partner had had a vasectomy; or (iv) had taken an oral contraceptive within 24 hours of the interview or according to instructions. Secondary outcomes were: (i) use of a long-acting contraceptive method (i.e. an intrauterine device, implant or permanent method); (ii) repeat pregnancy; (iii) repeat abortion; (iv) effective contraceptive use for more than 80% of the four or 12 months after the abortion; (v) road traffic accidents associated with the intervention (e.g. caused by driving while using the phone); and (vi) domestic abuse associated with the intervention (e.g. after the woman's husband or partner had listened to the messages). Research assistants contacted participants by phone and collected information on these outcomes using a standardized questionnaire. The effect of the intervention was examined in pre-specified subgroups categorized by age, urban or rural residence, educational level and socioeconomic status – access to a motorized

vehicle was used as a proxy measure of socioeconomic status. The four-month follow-ups were conducted between 13 August 2013 and 31 January 2014 and the 12-month follow-ups, between 24 July and 16 November 2014. An assessment of the validity of the self-reported data collected after four months in 50 participants will be reported elsewhere.

Statistical analysis

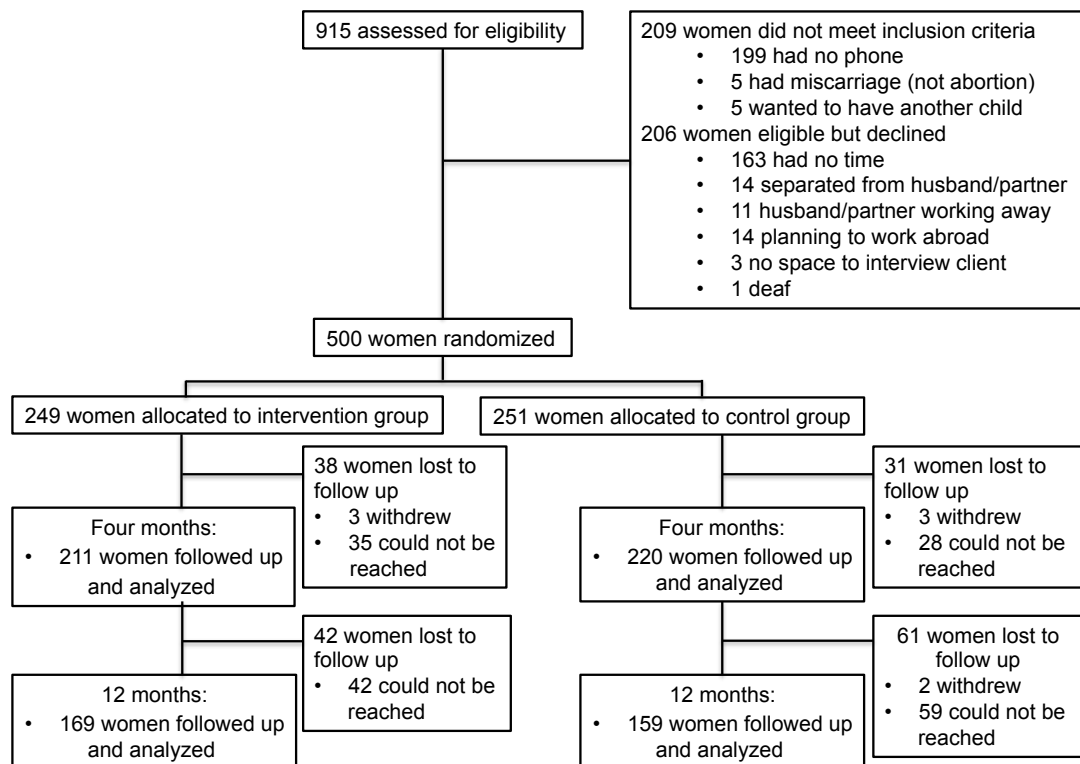
The statistical analysis plan was specified before the study was unblinded and was reported in the trial protocol.⁽¹⁶⁷⁾ We estimated that 35% of the control group would be using an effective contraception method after four months and that a sample size of 500 would be required to detect a 13% increase in contraceptive use with a 80%¹¹ power at the 5% level of significance.⁽¹⁶⁷⁾ Analyses were undertaken on an intention-to-treat basis using Stata version 13.1 (StataCorp. LP, College Station, United States of America). The effect of the intervention was expressed as a relative risk (RR) or hazard ratio (HR); a 95% confidence interval (CI) was used for primary and secondary outcomes and a 99% CI for subgroup analyses. The contraceptive discontinuation rate was assessed using Kaplan-Meier survival analysis techniques: for four-month follow-up data, discontinuation was assessed in participants who started using an effective contraception method during the first four weeks after an abortion and, for 12-month follow-up data, discontinuation was assessed in those who started the method during the three months after an abortion. Discontinuation was defined as stopping the method for one week or more before the four-month follow-up or for one month or more before the 12-month follow-up. If the participant switched from one effective method to another effective method this was not considered discontinuation.

¹¹ In the published paper power was reported as 90% (typo detected at the PhD viva)

5.4 Results

We excluded 199 potential participants because they did not own a mobile phone. Of the 500 participants, 249 were assigned to the intervention group and 251 to the control group (Figure 32).

Figure 32: Flowchart of participants



The participants' baseline characteristics are shown in Table 17. Data on the primary outcome were available for 431 (86%) participants at four months and for 328 (66%) at 12 months. Over 75% (133/172) of losses to follow-up by 12 months were due to the participant's phone being either switched off or not in use, as indicated by an automated message. Less frequently the phone number had been reassigned to another user or the participant had reportedly moved abroad for work. The proportion of women in the intervention group who reported effective contraception use was significantly higher than in the control group at four months

Table 17: Baseline characteristics of participants

Characteristic	Intervention group (n = 249)	Control group (n = 251)
	No. (%)	No. (%)
Age, years		
< 25	88 (35)	69 (27)
≥ 25	161 (65)	182 (73)
Residence		
Rural	164 (66)	157 (63)
Urban	85 (34)	94 (37)
Educational level		
None or primary school	93 (37)	103 (41)
Secondary school or higher	156 (63)	148 (59)
Socioeconomic status		
Access to a motorized vehicle	221 (89)	214 (85)
No access to a motorized vehicle	28 (11)	37 (15)
Marital status		
Married or cohabiting	231 (93)	233 (93)
Never married or cohabited	15 (6)	14 (6)
Divorced or separated	3 (1)	4 (2)
Literacy		
Able to recognize numbers	246 (99)	250 (100)
Not able to recognize numbers	3 (1)	1 (<1)
Number of living children		
0	79 (32)	68 (27)
1 or 2	122 (49)	131 (52)
≥3	48 (19)	52 (21)
Previous abortions		
0	144 (58)	155 (62)
1	69 (28)	65 (26)
≥2	36 (15)	31 (12)
Type of abortion before study entry		
Medical	102 (41)	105 (42)
Surgical	147 (59)	146 (58)
Woman planned to use contraception at time of randomization		
Yes	91 (37)	96 (38)
No	18 (7)	24 (10)
Undecided	140 (56)	131 (52)
Woman's mobile phone access		
Shares phone	123 (49)	118 (47)
Never shares phone	126 (51)	133 (53)

Inconsistencies arise in some values due to rounding.

(64% versus 46%, respectively; RR: 1.39; 95% CI: 1.17–1.66; Table 18) but not at 12 months (50% versus 43%, respectively; RR: 1.16; 95% CI: 0.92–1.47). Significantly more women in the intervention than the control group reported using a long-acting contraceptive method at four months (29% versus 9%, respectively; RR: 3.35; 95% CI: 2.07–5.40; Table 18) and at 12 months (25% versus 12%, respectively; RR: 2.08; 95% CI: 1.27–3.42). In addition, significantly more women in the intervention than the control group reported effective contraceptive use for more than 80% of the

Table 18: Effect of a mobile phone-based intervention on post-abortion family planning, Cambodia 2013-2014

Outcome	4-month follow-up			12-month follow-up		
	Interven tion	Control	RR (95% CI)	Interventi on	Control	RR (95% CI)
	No. (%)	No. (%)		No. (%)	No. (%)	
Primary outcome						
Self-reported use of an effective contraceptive method	135/211 (64)	101/220 (46)	1.39 (1.17–1.66)	84/169 (50)	68/159 (43)	1.16 (0.92–1.47)
Secondary outcome						
Use of a long-acting contraceptive method	61/211 (29)	19/220 (9)	3.35 (2.07–5.40)	42/169 (25)	19/159 (12)	2.08 (1.27–3.42)
Effective contraceptive use for > 80% of the follow-up period	108/200 (54)	81/203 (40)	1.35 (1.10–1.67)	86/169 (51)	61/159 (38)	1.33 (1.04–1.70)
Contraceptive discontinuation	9/123 (7)	16/101 (16)	0.45 ^a (0.20–1.01)	28/107 (26)	25/83 (30)	0.82 ^b (0.48–1.40)
Repeat pregnancy	6/210 (3)	5/220 (2)	1.25 (0.39–4.06)	22/169 (13)	28/159 (18)	0.74 (0.44–1.24)
Repeat abortion	2/210 (1)	1/220 (0.5)	2.10 (0.19–22.9)	8/169 (5)	11/159 (7)	0.68 (0.28–1.66)
Involvement in a road traffic accident	0/210 (0)	0/220 (0)	NA	ND	ND	NA
Experience of domestic abuse	0/210 (0)	0/220 (0)	NA	ND	ND	NA
Lost to follow-up ^b	38/249 (15)	31/251 (12)	1.24 (0.80–1.92)	80/249 (32)	92/251 (37)	0.88 (0.69–1.12)
Withdrawal from study	3/249 (1)	3/251 (1)	1.01 (0.21–4.95)	3/249 (1)	5/251 (2)	0.60 (0.15–2.50)

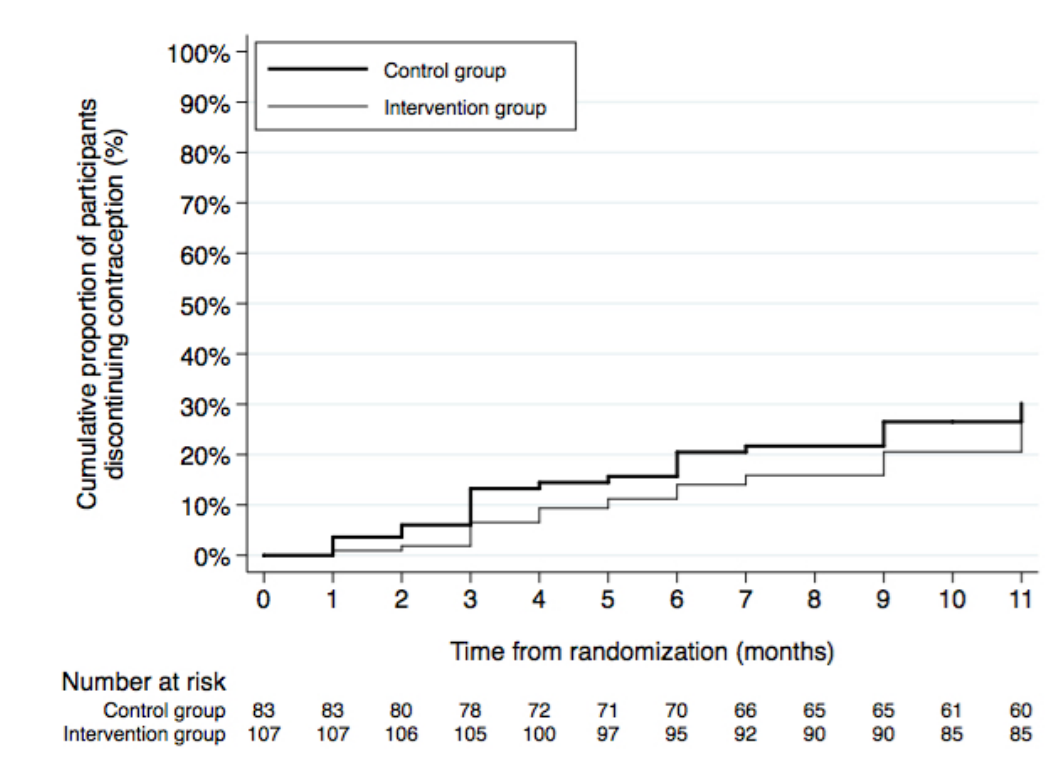
CI: confidence interval; NA: not applicable; ND: not determined; RR: relative risk.

^a The value for contraceptive discontinuation is the hazard ratio, not the relative risk.

^b The number lost to follow-up includes participants who withdrew from the study.

four months after the abortion (54% versus 40%, respectively; RR: 1.35; 95% CI: 1.10–1.67) and for more than 80% of the 12 months after (51% versus 38%, respectively; RR: 1.33; 95% CI: 1.04–1.70). There was some evidence that fewer women in the intervention than the control group had discontinued contraceptive use by the four-month follow-up (7% versus 16%, respectively; HR: 0.45; 95% CI: 0.20–1.01; Table 18) but not by the 12-month follow-up (26% versus 30%, respectively; HR: 0.82; 95% CI: 0.48–1.40; Figure 33).

Figure 33: Kaplan-Meier survival curves for contraceptive discontinuation



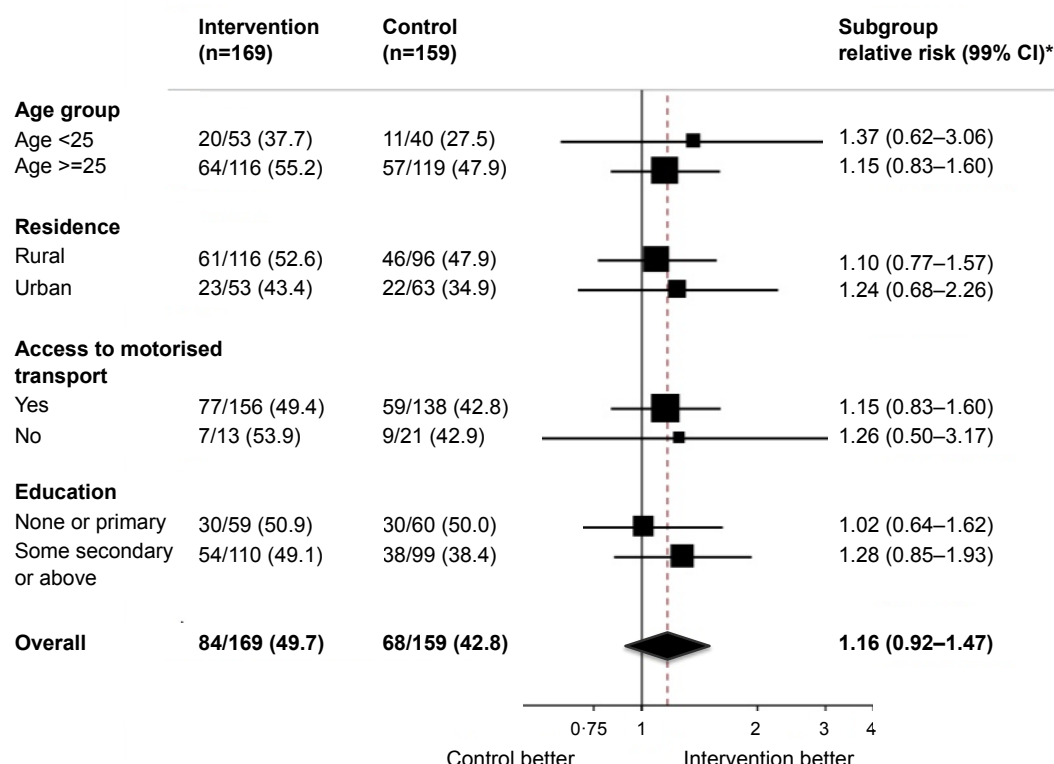
There was no significant difference between the groups in the proportion of women who had a repeat pregnancy or an abortion by four or 12 months and there were no reports that the intervention had been associated with a road traffic accident or domestic abuse at four months (Table 18).

The subgroup analysis found no evidence that either age, urban or rural residence, educational level or socioeconomic status influenced the effect of the intervention on contraception use at 12 months (Figure 34).

5.5 Discussion

Our mobile phone-based intervention was associated with an increase in the self-reported use of an effective contraceptive method four months after an abortion but not 12 months after. However, more participants in the intervention than the control group reported using a long-acting contraceptive method at four and 12 months. The intervention had no significant effect on the repeat pregnancy or abortion rate and

Figure 34: Contraception use in different subgroups at 12 months



there were no reports of adverse effects. This study has several strengths. First, all analyses were carried out on an intention-to-treat basis. Few trials of post-abortion family planning have a longer observation period than our study.(93) The follow-up rate at four months was high and there was no evidence of any difference in losses to follow-up between the treatment groups. However, the follow-up rate at 12 months was only 66%, which decreased the statistical power of our assessment of the long-term effects of the intervention. This low rate was probably due to participants migrating for work and/or changing phone numbers, which is recognized as a challenge for mobile phone-based interventions in Cambodia.(141)

One limitation of the study was that, since the intervention involved behavioural change, it was not possible to blind participants to their treatment allocation and they may have passed on information to the research assistants at follow-up. In addition, the use of self-report measures of contraceptive use has the potential for detection

bias. Although they are standard in contraceptive research, self-report measures have been shown to overestimate contraceptive use and underestimate abortion rates.⁽¹⁸⁸⁾ However, it seems unlikely that participants would over-report using one particular long-acting method rather than another (e.g. intrauterine devices versus implants). It was not feasible to measure objective contraception use in this setting and electronic medication monitors and hormonal assays have limited reliability and validity.⁽²¹⁴⁾⁽¹⁸⁹⁾ Oral and injectable contraceptives can be obtained from pharmacists without prescriptions in Cambodia, so clinic records may not accurately reflect contraceptive use. The most commonly reported reason for ineligibility was not having a mobile phone. Although we did not record the characteristics of the 199 potential participants in our study who did not have a phone, it is a concern that mobile phone-based interventions may not reach the people most in need. We did not give participants mobile phones because of possible implications for the sustainability of the intervention and because there could have been negative consequences for a participant if she was asked where she obtained a new phone. Study participants were similar to clients seeking abortion services at the four Marie Stopes International Cambodian study clinics during 2013. Most of these women are married and multiparous, had attended secondary school, are aged over 25 years and have previously paid for reproductive health services at a clinic run by a nongovernmental organization. However, sex workers – known to have a high unmet need for contraception and a high abortion rate⁽⁹¹⁾ – and young women, were not well represented in our study population. The effect of mobile phone-based interventions on post-abortion family planning among these groups requires further evaluation. There are few trials of mobile phone-based interventions to increase contraception

use. Two small trials found no effect,(143)(144) whereas one trial found improved self-reported adherence to oral contraceptive use.(142) Service providers often define post-abortion family planning as the initiation of contraceptive use within two weeks of an abortion but we did not identify any trials reporting follow-up at this time point. We decided to assess contraception use at four months, after the intervention had been completed, because we recognized that side-effects and discontinuation are common in the first few months.(16) The 12-month follow-up was intended to assess the long-term effects of the intervention. Although at 12 months there was no evidence of increased contraceptive use overall or of less frequent discontinuation, our intervention was associated with an increase in the use of long-acting contraceptive methods in a context where a wide range of post-abortion family planning methods is available but the immediate uptake of contraception is low (data available from corresponding author). The increase occurred because participants returned to the clinic for a contraceptive implant or an intrauterine device and is consistent with our findings that some clients preferred to make decisions about post-abortion family planning after discharge from clinical care.(212) As our intervention was complex, it was not clear which component influenced the uptake of long-acting methods. It is plausible, though, that a relatively intensive intervention delivered over a short period of time could influence the decision to adopt a long-acting method (i.e. a single behavioural change) but be less effective in influencing continued adherence to an oral contraceptive, which requires sustained repetitive behaviour. In fact, the literature suggests that interventions encouraging medication adherence are more effective for short-term rather than long-term treatments. Furthermore, long-acting contraceptive methods are associated with lower discontinuation rates than short-

acting hormonal methods.(16)(134)(215) We plan to publish a separate report on the results of qualitative interviews with participants about their experience of the intervention. Few studies have examined contraceptive use for an extended period after an abortion in a low-income setting. One matched, controlled study in Zimbabwe assessed the effect of counselling and free contraception before hospital discharge. At 12 months, effective contraceptive use was higher in the intervention than the control group (84% (227/271) versus 64% (165/258), respectively; $P < 0.001$) and repeat unintended pregnancy was lower (15% (42/276) versus 34% (96/281), respectively; $P < 0.001$) but repeat abortions were not significantly lower (3% versus 5%; $P = 0.23$).⁽⁹⁸⁾ At 12 months in our study, 13% (22/169) of participants in the intervention group reported a repeat pregnancy compared with 18% (28/159) in the control group; the corresponding figures for a repeat abortion were 5% (8/169) and 7% (11/159), respectively. However, the study was not powered to detect differences in these outcomes. Nevertheless, the increased use of long-acting methods and the increased duration of all effective contraceptive use would be expected to result in a decrease in unintended pregnancies and repeat abortions over time. A larger study may be able to detect differences in these outcomes.

Conclusion

Our results indicate that the addition of a mobile phone-based intervention to existing abortion care services could increase the use of long-acting contraceptives. The overall use of effective contraceptive methods was increased four months after an abortion but not at 12 months. In practice, the duration, language and mode of communication (i.e. text or voice) could be adapted to different settings, though voice messages will be most useful in populations with limited literacy. We estimated the main cost of

delivering the intervention (i.e. for voice messages, phone calls and the counsellors' time) to be 6 United States dollars per client. A cost–effectiveness analysis will be reported elsewhere. Although our intervention was delivered in addition to post-abortion family planning support at a clinic, future research could assess the effect of a similar intervention in settings with more limited support: for example, where medical abortions are provided by the private sector.

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Competing interests

None declared.

5.6 Additional trial analysis

This section contains additional trial analysis; either pre-specified analysis that was cut by journals due to word count limitations, or exploratory analyses of the dynamics of contraception use over the post-abortion period. The aim of this analysis is to further understand the patterns of contraceptive use over the post-abortion period, in particular differences in uptake, discontinuation and switching between the intervention and control groups.

General trends in method mix

Figure's 35-39 and Table 19 are exploratory analyses that show the contraceptive method mix at two weeks and at four and 12 months. Contraception use appears to be most dynamic during the first 10 weeks post-abortion; particularly in the intervention group where use of effective methods increases and no/non-effective method use decreases. Over the 12-month period, no/non effective method use increases in both groups as use of effective methods are stable or decreasing.

Use of long-acting methods (IUD and implant¹²) are consistently increased in the intervention group at all time points. Use of non-effective methods appear to be higher in the control group at four and 12 months, but there appears to be little difference between use of no method at four and 12 months. Injectable use is similar at two weeks post-abortion, but use appears higher in the intervention group at four and 12 months. Conversely, oral contraceptive use in the intervention and control groups is similar at two weeks but use appears higher in the control group at four and 12 months. It is unclear from these figures and tables whether women who

¹² Only one trial participant had a permanent method of contraception (in the control group and hence the discussion of 'long-acting' methods in this section refers to IUD and implant)

discontinued a particular method such as OC stopped using the method altogether or switched to an alternative effective method.

Figure 35: Contraception use over the 4-month post-abortion period: intervention group

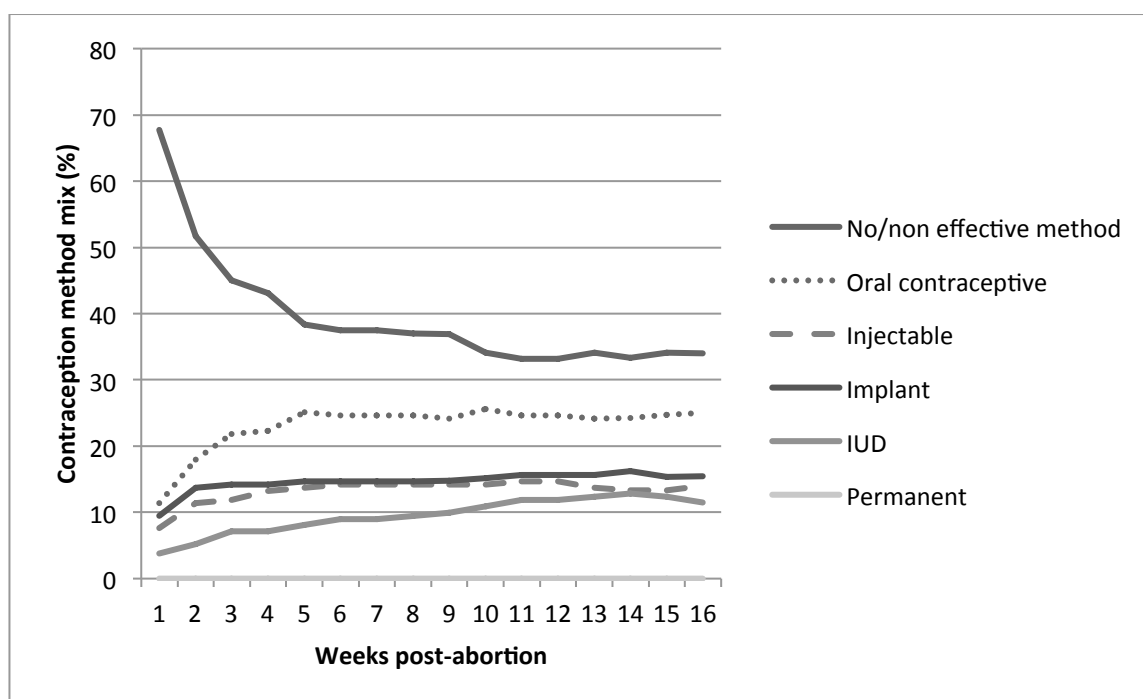


Figure 36: Contraception use over the 4-month post-abortion period: control group

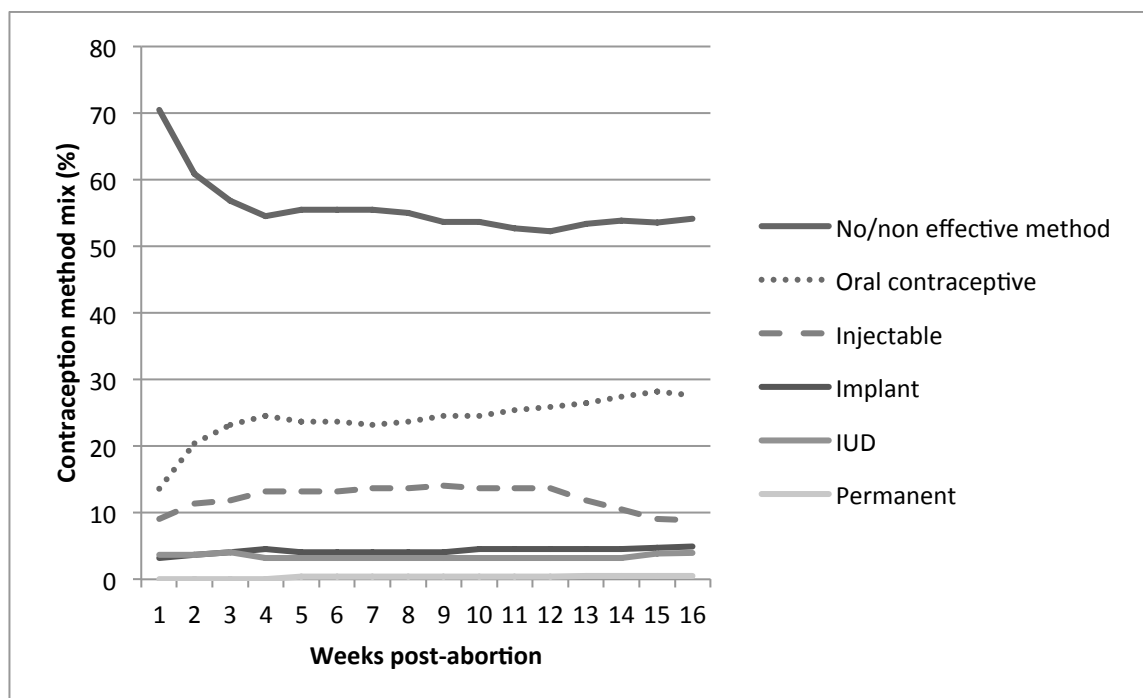


Figure 37: Contraception use over the 12-month post-abortion period: intervention group

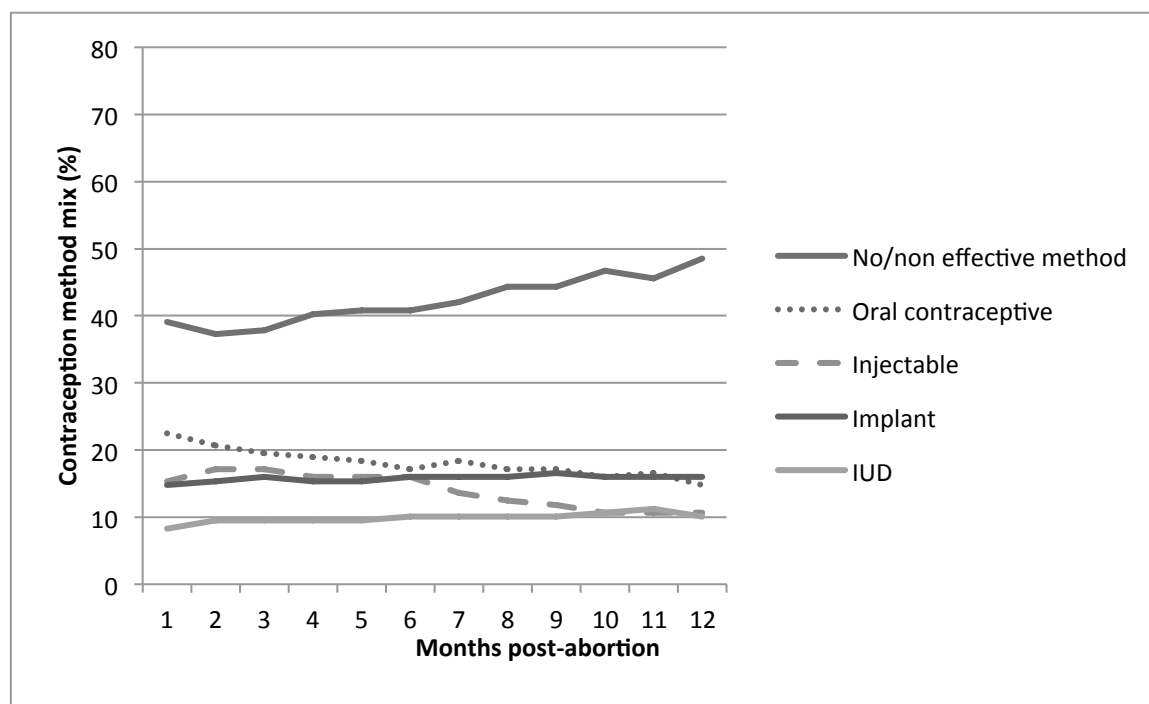
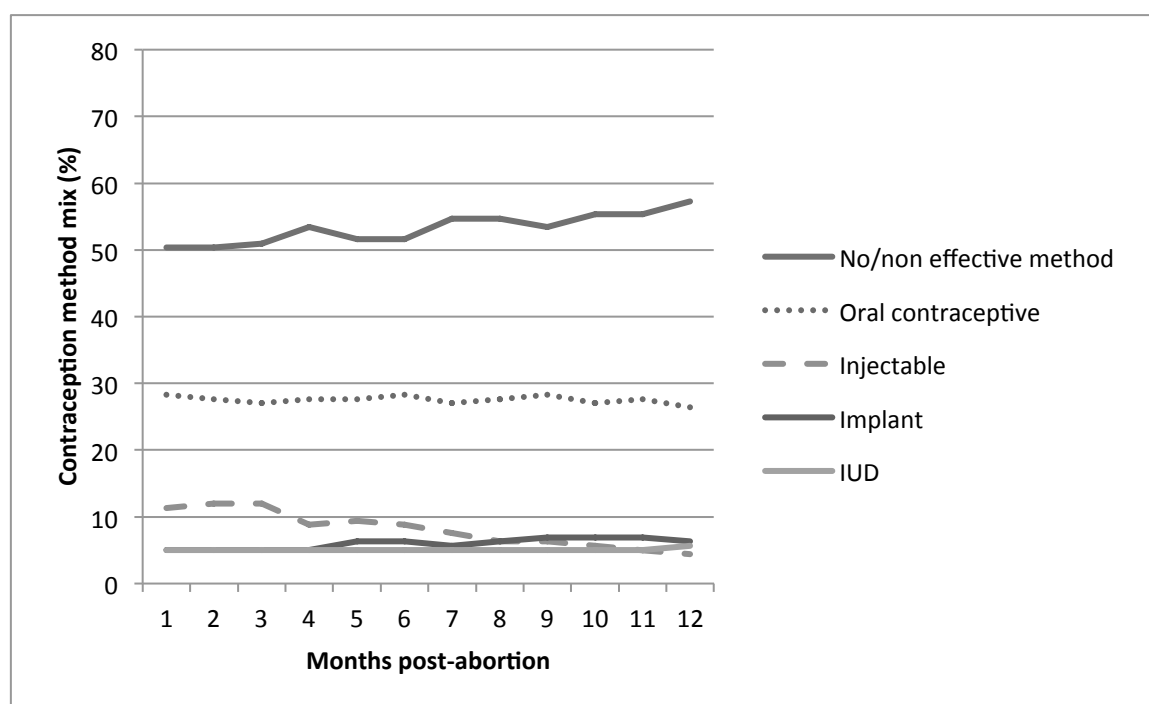


Figure 38: Contraception use over the 12-month post-abortion period: control group



At two weeks, overall use of effective contraception was 39% (Table 19) which is similar to the 40% use of effective contraception at two weeks found in the case note review as part of the formative research to develop the intervention.(212)

Figure 39: Contraceptive method mix at 2 weeks, 4 and 12 months

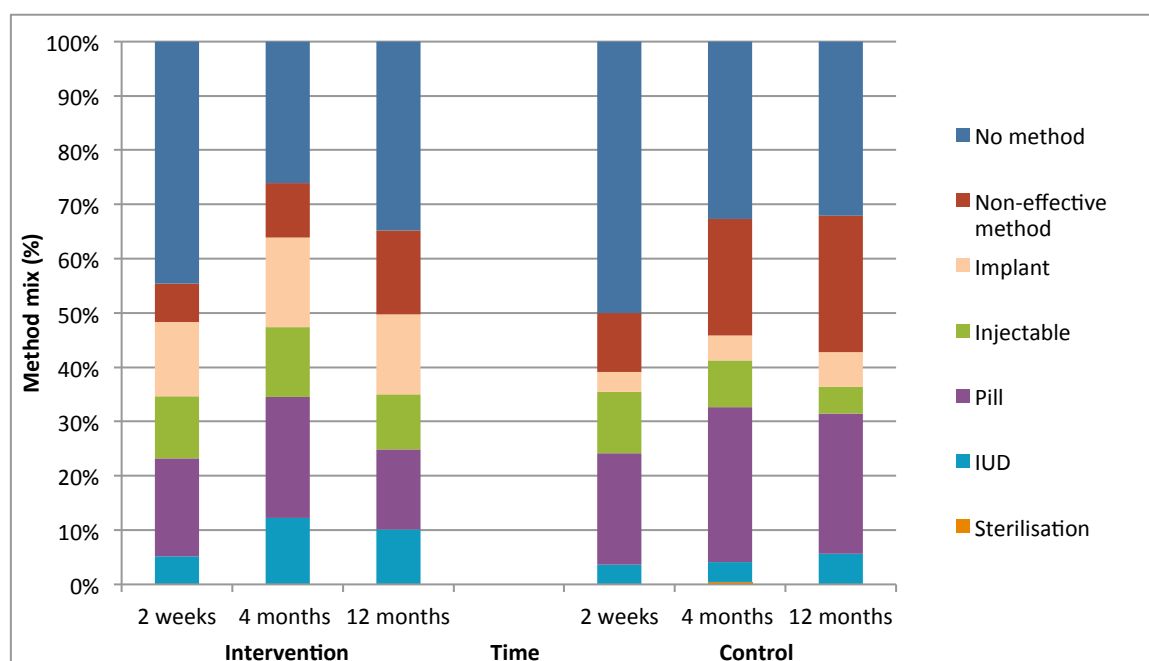


Table 19: Contraceptive method mix at 2 weeks, 4 and 12 months

	Intervention	Control	P	Intervention	Control	P	Intervention	Control	P
	No. (%)	No. (%)	value	No. (%)	No. (%)	value	No. (%)	No. (%)	value
	2 weeks			4 months			12 months		
Oral contraceptive	38 (18%)	45 (20%)	0.006	47 (22%)	63 (29%)	<0.001	25 (15%)	41 (26%)	0.002
Injection	24 (11%)	25 (11%)		27 (13%)	19 (9%)		17 (10%)	8 (5%)	
Implant	29 (14%)	8 (4%)		35 (17%)	10 (5%)		25 (15%)	10 (6%)	
Intra-uterine device	11 (5%)	8 (4%)		26 (12%)	8 (4%)		17 (10%)	9 (6%)	
Permanent method	0 (0%)	0 (0%)		0 (0%)	1 (0.5%)		0 (0%)	0 (0%)	
Non-effective method	15 (7%)	24 (11%)		21 (10%)	47 (21%)		26 (15%)	40 (25%)	
No method	94 (45%)	110 (50%)		55 (26%)	72 (33%)		59 (35%)	51 (32%)	
Total effective methods	102 (48%)	86 (39%)		135 (64%)	101 (46%)		84 (50%)	68 (43%)	

Four and 12-month data based on current use at follow up. Method mix at 2 weeks based on calendar data collected at four-month follow up. Non-effective methods included condom, withdrawal, rhythm (calendar) and other traditional methods. The participant that reported permanent method at four months was not followed up at 12 months.

Initiation of long-acting contraception

Figure 40 and Table 20 are exploratory analyses that show initiation of long-acting methods (IUD or implant) over the four-month post-abortion period. The data was obtained

retrospectively at four months asking participants about weekly contraceptive use.

Initiation of a long-acting method during the first four weeks post-abortion was higher amongst women receiving the intervention compared to those receiving standard care (59/211 (28%) intervention vs. 20/218 (9%) control (RR 3.05 (95% CI 1.90 – 4.88); $p < 0.001$).

Figure 40: Initiation of long-acting methods (IUD/implant) over 4-month post-abortion period

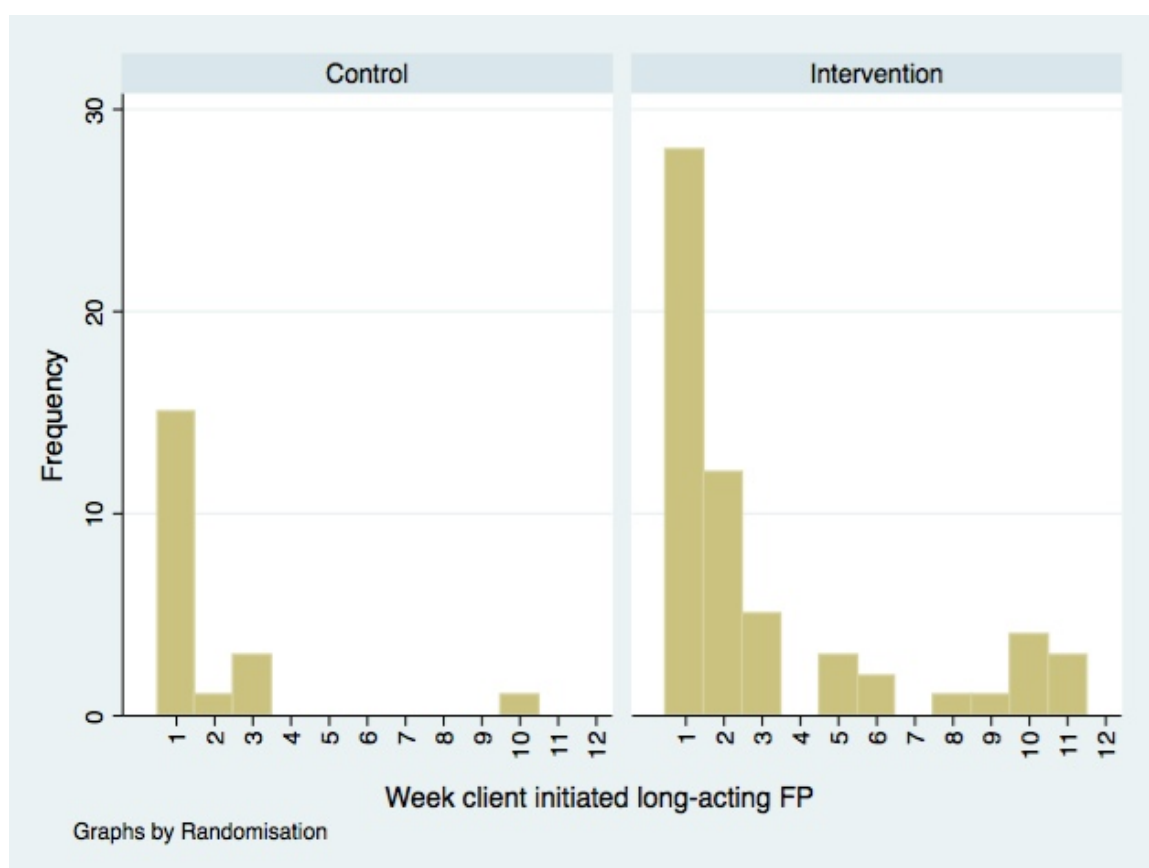


Table 20: Initiation of long-acting contraception over the 4-month post-abortion period

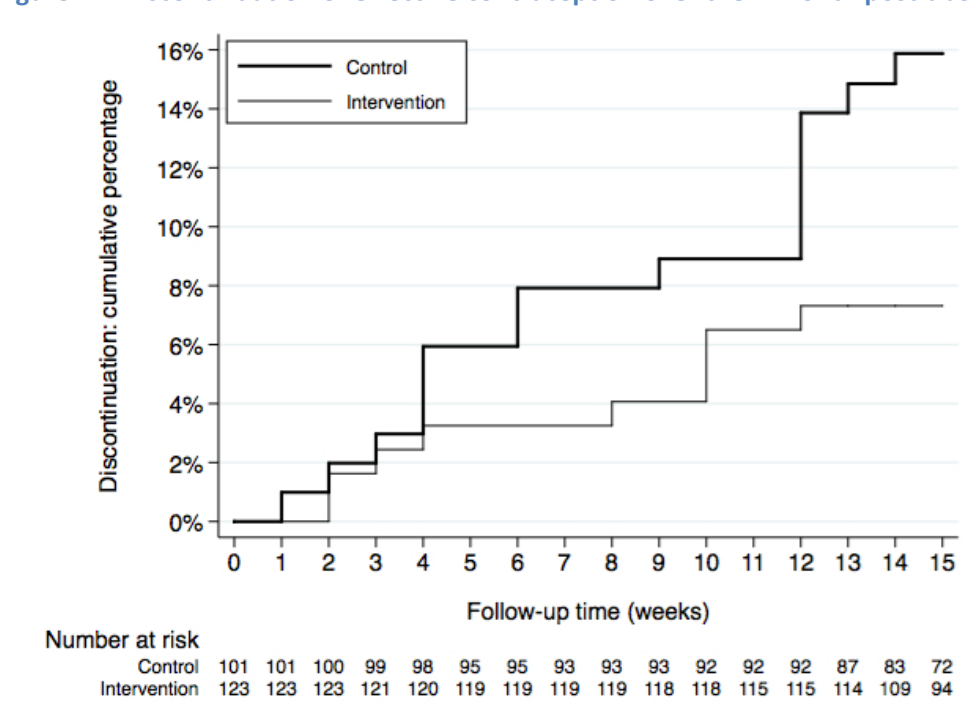
Week	Implant		IUD		Total long-acting contraception (implant + IUD)			
	Intervention	Control	Intervention	Control	Intervention	Control	RR (95% CI)	P value
1	20	7	8	8	28	15		
2	9	1	3	0	12	1		
3	1	1	4	2	5	3		
4	0	0	0	0	0	0		
5	1	0	2	0	3	0		
6	0	0	2	0	2	0		
7	0	0	0	0	0	0		
8	0	0	1	0	1	0		
9	0	0	1	0	1	0		
10	1	1	3	0	4	1		
11	1	0	2	0	3	0		
12	0	0	0	0	0	0		
Total	33	10	26	10	59/211 (28%)	20/218 (9%)	3.05 (1.90-4.88)	<0.001

In the control group it appears that initiation of long-acting methods occurred mainly during the first three weeks. In the intervention group initiation of long-acting methods is also most frequent during the first three weeks, but continued uptake over the 12-week period can be observed. The finding that initiation appeared to be higher during the first week in the intervention group compared to the control group could be explained by women returning within a few days of receiving the intervention to initiate methods. However, the observed increased uptake during week one could be due to recall bias, for example, if initiation was after one to two weeks but recalled to be within one week.

Discontinuation

The following set of tables and figures show contraceptive discontinuation over the follow up period. Figure 41 shows discontinuation of effective contraception over the four-month period; a pre-specified analysis cut from the main trial paper due to lack of space. Discontinuation of effective contraception over the 12-month period was reported in the main trial paper. The analysis included 224 participants starting an effective method of contraception during the first four weeks post-abortion using data collected at four-month follow up. Discontinuation was defined as stopping effective contraception for one week or more during the following 15 weeks. If the participant switched from one effective method to another effective method this was *not* considered discontinuation. There was some evidence of reduced discontinuation amongst participants receiving the intervention (9/123 (7%) vs. 16/101 (16%) hazard ratio 0.45, 95% CI 0.20-1.01; $p=0.053$). However, the extent to which women discontinued specific methods and switched between methods is unclear from Figure 41.

Figure 41: Discontinuation of effective contraception over the 4-month post-abortion period



Kaplan-Meier analysis. Number at risk refers to users of contraception at each time point. Log-rank test for equality of survivor functions (compares observed and expected events) $p=0.048$

Method-specific discontinuation

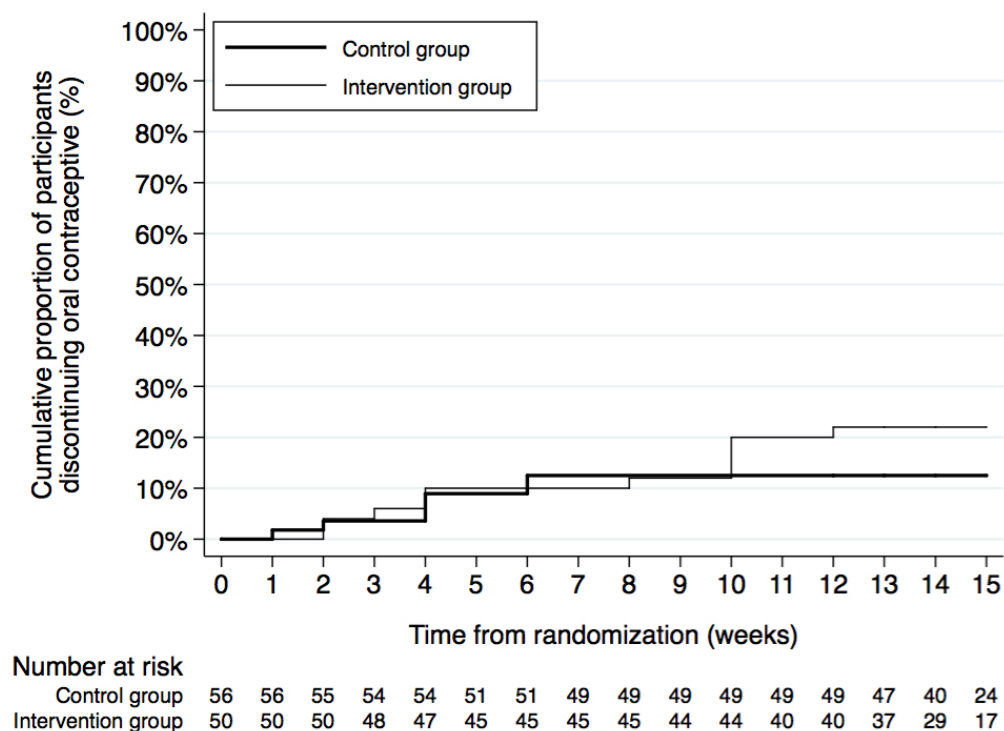
Table 21 and Figures 42 to 44 are exploratory analyses that show method-specific discontinuation during the four-month post abortion period. Although not statistically significant, a trend can be observed towards increased OC discontinuation in the intervention group (22% intervention vs. 13% control) and increased injectable discontinuation in the control group (14% intervention vs. 36% control). The numbers of IUD discontinuation are too small to comment on and there were no cases of implant discontinuation.

Table 21: Method specific discontinuation at 4 months

Outcome	Overall	Intervention	Control	Hazard Ratio	P value
OC discontinuation	18/106 (17%)	11/50 (22%)	7/56 (13%)	1.82 (0.71-4.70)	0.208
Injectable discontinuation	14/56 (25%)	4/28 (14%)	10/28 (36%)	0.39 (0.12-1.26)	0.098
Implant discontinuation	0/39 (0%)	0/30 (0%)	0/9 (0%)		
IUD discontinuation	4/25 (16%)	1/15 (7%)	3/10 (30%)	0.17 (0.02-1.68)	0.097
Total	36/226 (16%)	16/123 (13%)	20/103 (19%)		

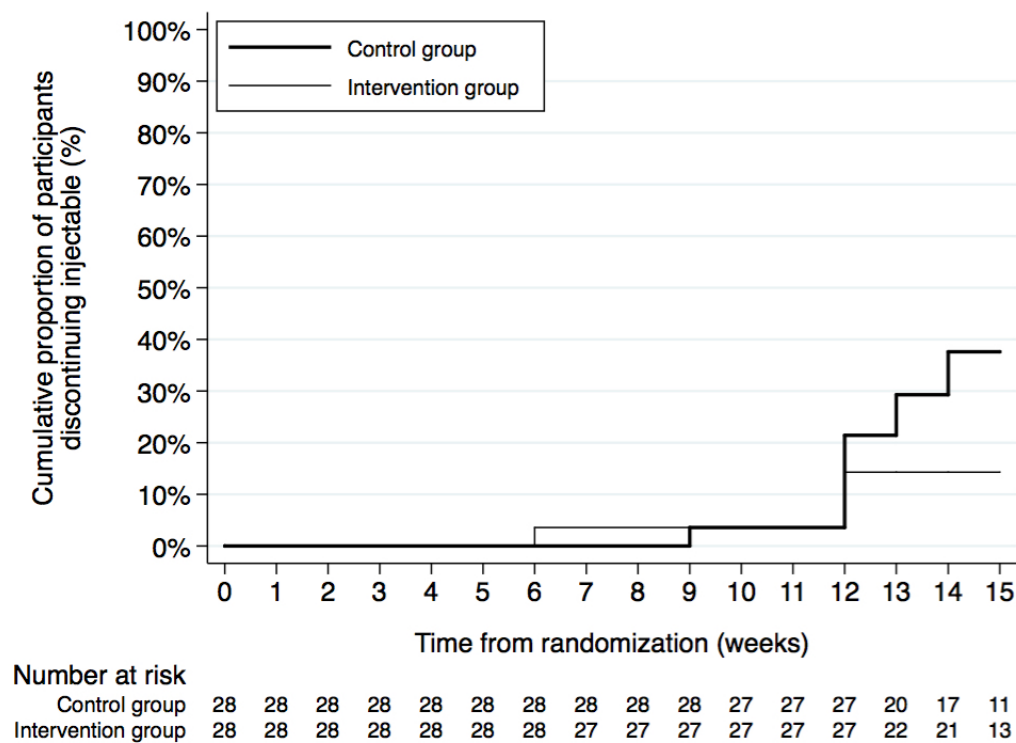
*Includes participants that started method during first 4 weeks post-abortion. Discontinuation defined as stopping the method for one week or more during the following 15 weeks

Figure 42: Oral contraceptive discontinuation at 4 months



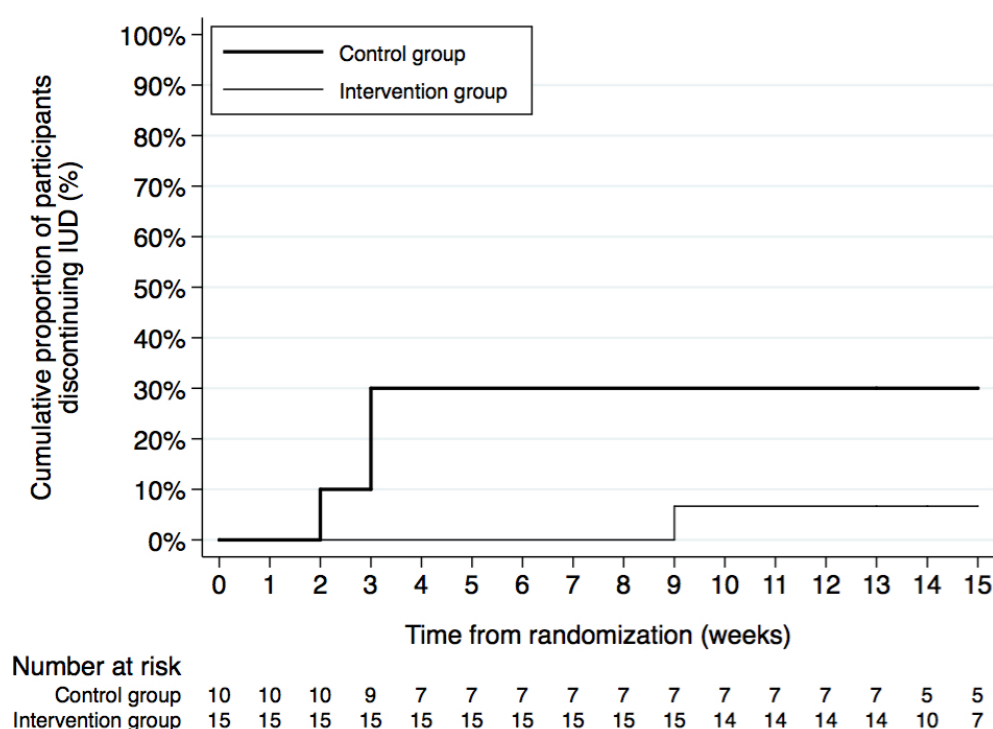
Kaplan-Meier analysis. Number at risk refers to users of oral contraceptive at each time point. Log-rank $p=0.224$

Figure 43: Injectable discontinuation at 4 months



Kaplan-Meier analysis. Number at risk refers to users of injectable at each time point. Log rank $p=0.079$

Figure 44: IUD discontinuation at 4 months



Kaplan-Meier analysis. Number at risk refers to users of IUD at each time point. Log rank $p=0.107$

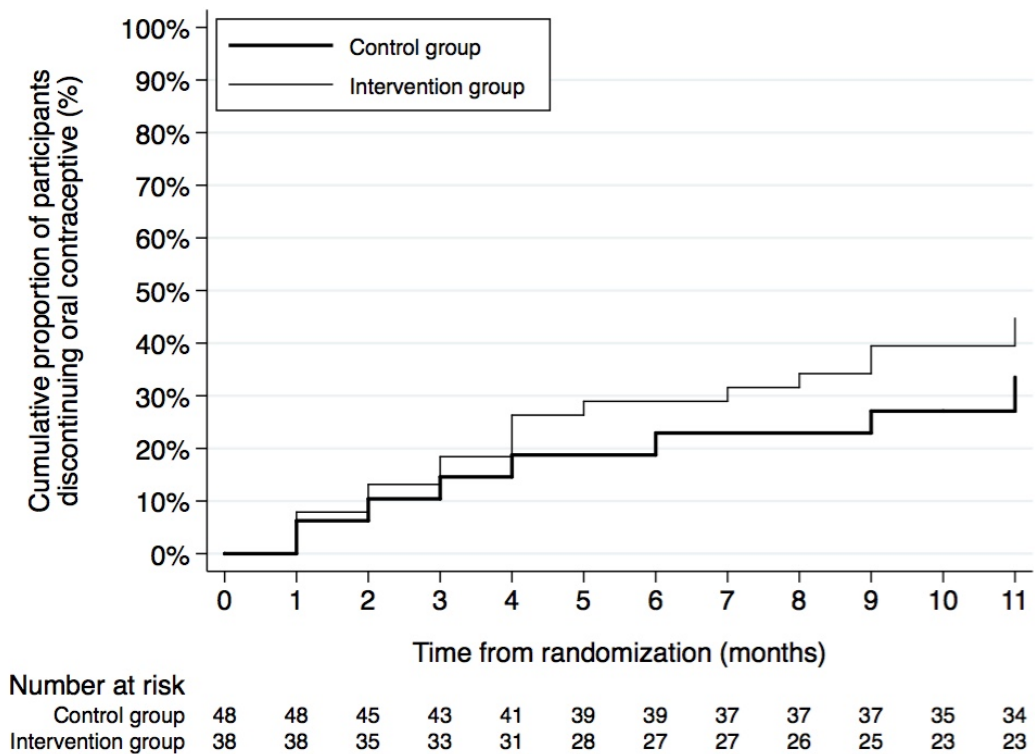
Table 22 and Figures 45 to 48 are exploratory analyses that show method-specific discontinuation during the 12-month post abortion period. Overall, discontinuation rates are higher for OC and injectable and lower for implant and IUD. These rates are broadly consistent with the approximate 30% and 10% discontinuation for hormonal methods and IUD respectively observed elsewhere.(87)(16)

Table 22: Method specific discontinuation at 12 months

Outcome	Overall	Intervention	Control	Hazard Ratio	P value
OC discontinuation	33/86 (38%)	17/38 (45%)	16/48 (33%)	1.46 (0.74-2.90)	0.275
Injectable discontinuation	30/48 (63%)	16/29 (55%)	14/19 (74%)	0.57 (0.28-1.18)	0.129
Implant discontinuation	4/35 (11%)	2/27 (7%)	2/8 (25%)	0.29 (0.04-2.04)	0.213
IUD discontinuation	3/24 (13%)	2/16 (13%)	1/8 (13%)	0.94 (0.08-10.32)	0.957
Total	70/193 (36%)	37/110 (34%)	33/83 (40%)		

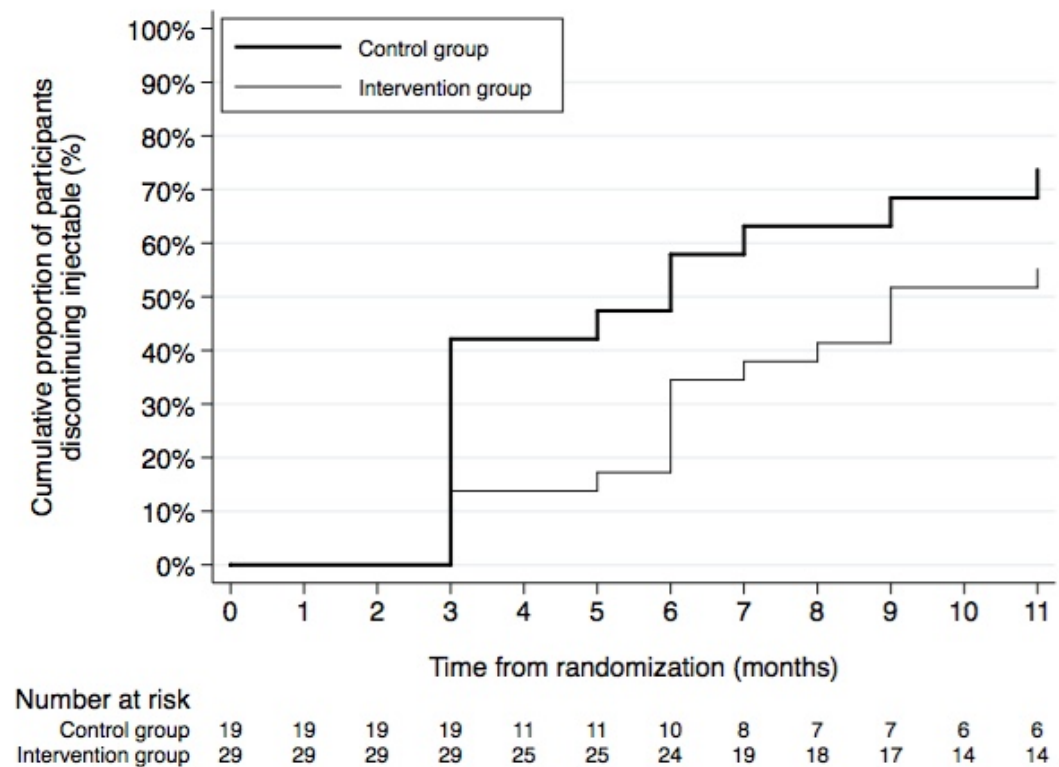
*Includes participants that started method during first 4 months post-abortion. Discontinuation defined as stopping effective contraception for one month or more during the following 11 months

Figure 45: Oral contraceptive discontinuation at 12 months



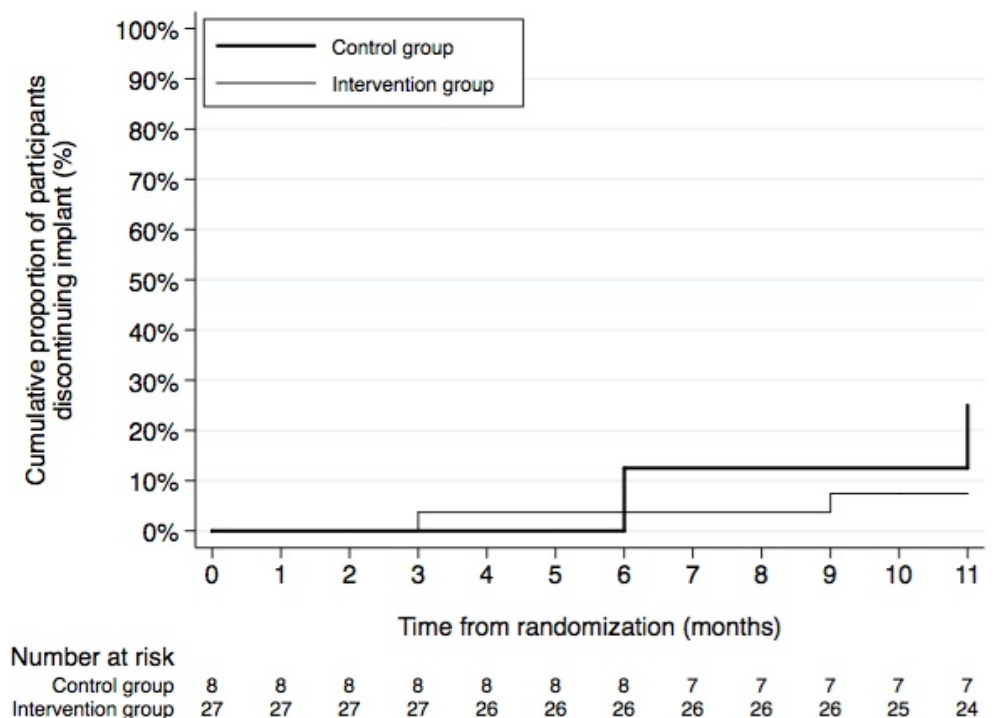
Kaplan-Meier analysis. Number at risk refers to users of oral contraception at each time point. Log rank $p=0.278$

Figure 46: Injectable discontinuation at 12 months



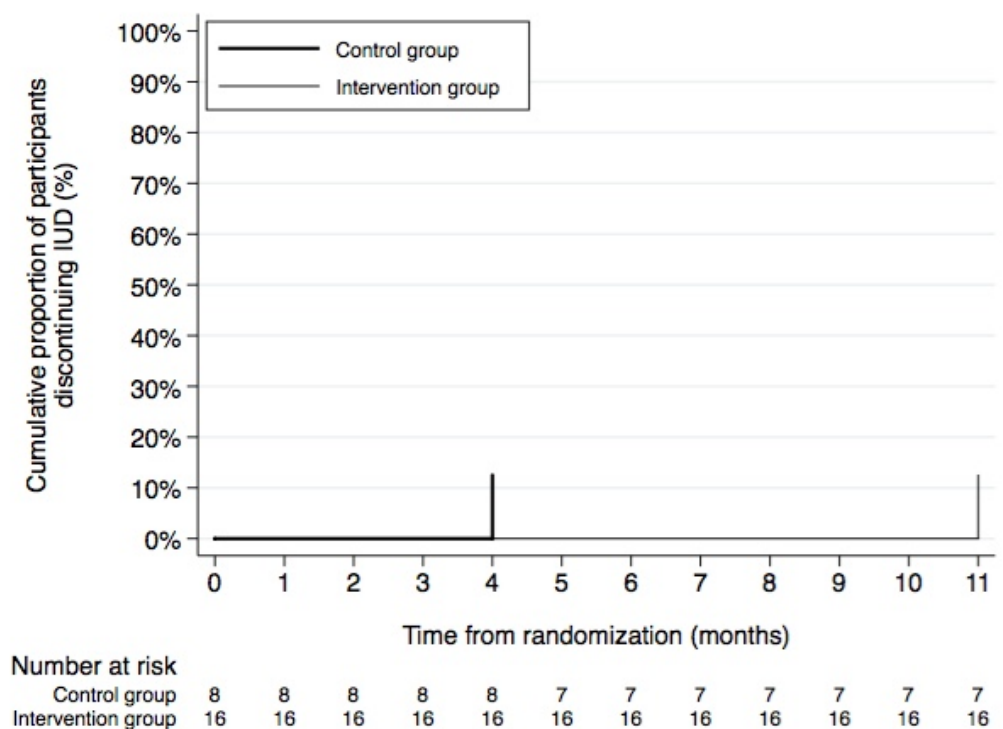
Kaplan-Meier analysis. Number at risk refers to users of injectable at each time point. Log rank $p=0.093$

Figure 47: Implant discontinuation at 12 months



Kaplan-Meier analysis. Number at risk refers to users of implant at each time point. Log rank $p=0.189$

Figure 48: IUD discontinuation at 12 months



Kaplan-Meier analysis. Number at risk refers to users of injectable at each time point. Log rank $p=0.942$

Again, although not statistically significant, a trend can be observed towards increased OC discontinuation in the intervention group (45% intervention vs. 33% control) and increased injectable discontinuation in the control group (55% intervention vs. 74% control).

Increased injectable discontinuation can be observed at three-months as would be expected when women would be expected to return for a repeat injection. The numbers of IUD and implant discontinuation are too small to comment on. However, it remains unclear from these figures and tables whether women who discontinued OC and injectable switched to an alternative effective method.

Switching

Table 23 is an exploratory analysis that shows the number and proportion of women that discontinued an effective method and switched to a different effective method at four and 12 months.

Table 23: Method switching if discontinued an effective method

	4 months		RR (95% CI)	12 months		RR (95% CI)
	Intervention	Control		Intervention	Control	
OC	3/11 (27%)	0/7 (0%)		6/17 (35%)	3/16 (19%)	
Injectable	3/4 (75%)	2/10 (20%)		5/16 (31%)	5/14 (36%)	
Implant	N/A	N/A		1/2 (50%)	0/2 (0%)	
IUD	1/1 (100%)	2/3 (67%)		0/2 (0%)	1/1 (100%)	
Total	7/16 (44%)	4/20 (20%)	2.19 (0.77-6.18)	12/36 (33%)	9/33 (27%)	1.22 (0.59-2.52)

During the four-month post-abortion period, 44% of women who discontinued an effective method switched to a different effective method in the intervention group compared to 20% in the control group (RR 2.19; 95% CI 0.77-6.18). During the 12-month post-abortion period, 33% of women who discontinued an effective method switched to a different effective method in the intervention group compared to 27% in the control group (RR 1.22; 95% CI 0.59-2.52). These differences are not statistically

significant but suggest a trend towards increased safe-method switching amongst women receiving the intervention.

The data in Table 23 suggests a trend toward increased safe-switching, at four and to a lesser extent 12-months, amongst women receiving the intervention. Thus, the trend towards decreased OC use in the intervention group at four and 12 months could be explained by women switching to other more effective methods. However, it is also possible that the increased discontinuation of OC in the intervention group was due to the intervention content (voice messages and phone calls) encouraging use of longer-acting methods in preference to OC.

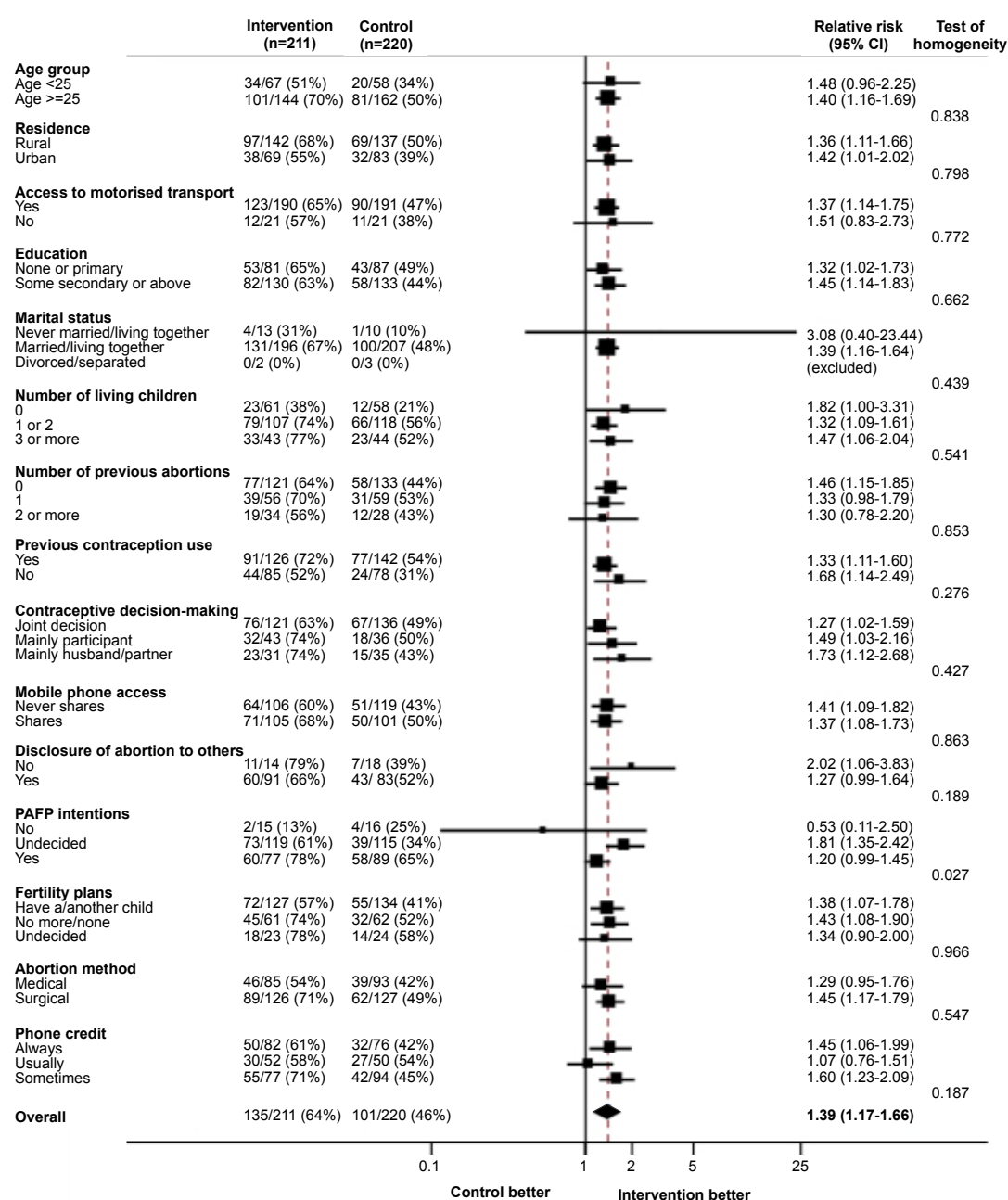
Subgroup analysis

Figure 49 is an exploratory analysis showing the effect of intervention on primary outcome amongst different subgroups at four-months, expressed as a relative risk with a 95% confidence interval. The pre-specified analysis included only age, SES, residence and education and was cut from the main trial paper due to lack of space. The effect of the intervention amongst pre-specified subgroups categorised by age, residence, educational level and socio-economic status analysis at 12 months was reported in the main trial paper.(203)

There was no evidence of heterogeneity (i.e. that the effect of the intervention varied amongst any subgroups) apart from PAFP intentions at the time of seeking abortion services ($p=0.027$); the intervention was associated with a statistically significant increase in effective contraception use at four-months amongst women who were undecided about PAFP at the time of seeking abortion services, which suggests that the intervention was particularly effective amongst this group of women. The

intervention was associated with a smaller increase in effective contraception use at four-months amongst women planning to use PAFP at the time of seeking abortion

Figure 49: Effect of the intervention on the primary outcome at 4 months amongst different subgroups



services, but this was not statistically significant. Conversely, there was no evidence

that the intervention was effective in women who were not planning to use PAFP, although the confidence interval was wide for this group due to few numbers.

There are several reasons why the intervention might not be effective in women not planning to use PAFP. First, it is possible that the circumstances of the pregnancy were different, for example that they were seeking abortion services because of a pregnancy complication rather than an unintended pregnancy and therefore planned another pregnancy in the future. Second, it is possible that these women were not planning to use contraception due to a perceived low likelihood of subsequent pregnancy because their circumstances had changed perhaps due a relationship breakdown or infrequent sexual intercourse. Third, it is possible that this group of women included those who preferred not to use contraception and opt to seek abortion services for a subsequent pregnancy. Further research could examine the characteristics of women seeking abortion services that do not plan to use PAFP.

Comparing baseline characteristics of study participants with MSI clinic population

Table 24 compares baseline characteristics of trial participants with MSI Cambodia clinic clients, based on available comparable data. Presentation of this data was suggested by a peer-reviewer, but the table was cut from the main trial paper due to space limitations.

It can be observed that the study population was of similar age and parity compared with MSI clients seeking abortion services at the four study clinics during 2013; mainly married, multiparous, secondary educated women aged >25 paying for reproductive health services at an non-governmental organisation clinic. The study population and broader MSI population were similar for several of the occupation categories such as entertainment worker, factory worker, student, farmer and unemployed but there

appeared to be increased proportions of employed and self-employed and a decreased proportion of housewives in the study population. This may have been because women in the employed and self-employed categories were more likely to own their own phone and be able to receive the intervention and hence join the study, but this can not be confirmed from the available data.

Table 24: Comparison of baseline characteristics of trial participants with Marie Stopes International (MSI) Cambodia clinic clients

	Trial intervention group	Trial control group	MSIC clients
Age (years)			
<25	88/249 (35%)	69/251 (27%)	2159/6592 (33%)
25 or more	161/249 (65%)	182/251 (73%)	4433/6592 (67%)
Number of living children			
0	79/249 (32%)	68/251 (27%)	2248/6592 (34%)
1-2	122/249 (49%)	131/251 (52%)	2956/6593 (45%)
3 or more	48/249 (19%)	52/251 (21%)	1389/6593 (21%)
Previous abortions			
0	144/249 (58%)	155/251 (62%)	3302/6587 (50%)
1	69/249 (28%)	65/251 (26%)	1885/6587 (29%)
2 or more	36/249 (14%)	31/251 (12%)	1400/6587 (21%)
Type of abortion			
Medical	102/249 (41%)	105/251 (42%)	2384/6594 (36%)
Surgical	147/249 (59%)	146/251 (58%)	4210/6594 (64%)
Occupation			
Employed	55/249 (22%)	44/251 (18%)	513/6594 (8%)
Entertainment worker	11/249 (4%)	16/251 (6%)	341/6594 (5%)
Factory worker	43/249 (17%)	33/251 (13%)	1181/6594 (18%)
Farmer	10/249 (4%)	22/251 (9%)	620/6594 (9%)
Housewife	47/249 (19%)	55/251 (22%)	2515/6594 (38%)
Self-employed	68/249 (27%)	66/251 (26%)	1068/6594 (16%)
Student	9/249 (4%)	8/251 (3%)	174/6594 (3%)
Unemployed	4/249 (2%)	5/251 (2%)	6/6594 (0.1%)
Other	2/249 (1%)	2/251 (1%)	176/6594 (3%)

Summary data of all clients seeking abortion services during 2013 at the four MSIC study clinics (where available and comparable)

Regarding generalisability beyond MSI clinics, the 2014 Cambodia DHS reported data on where there most recent abortion took place (public health facility, private health facility, respondent home, and other home) according to background characteristics of age, pregnancy duration, residence and education.(74) As mentioned in Section 1.2, overall, 44% of women used a private facility, compared to 16% who used a public facility, 32% who had an abortion at home and 8% who had an abortion at another home. Private facilities include both non-governmental organisation clinics and those

operated by private healthcare workers, and thus these data are limited in terms of providing a complete picture of which women seek abortion services where, but do however provide some insights regarding generalisability of the study population beyond MSI clinics. It is likely that a significant proportion of women having an abortion at a home were using medical abortion and it is not clear from the DHS data where the women obtained the drugs. However, some observations can be made. The proportion of women having an abortion in a private health facility did not appear to differ markedly by age (45% aged 15-34 versus 43% aged 35-49) or residence (46% urban versus 44% rural) but did appear to vary by education (39% no education versus 45% primary and higher). There was a trend towards younger women, rural women and those with increased education being less likely to use a public health facility (13% aged 15-34 versus 19% aged 35-49; 15% rural versus 18% urban; 19% no education versus 15% primary and higher).

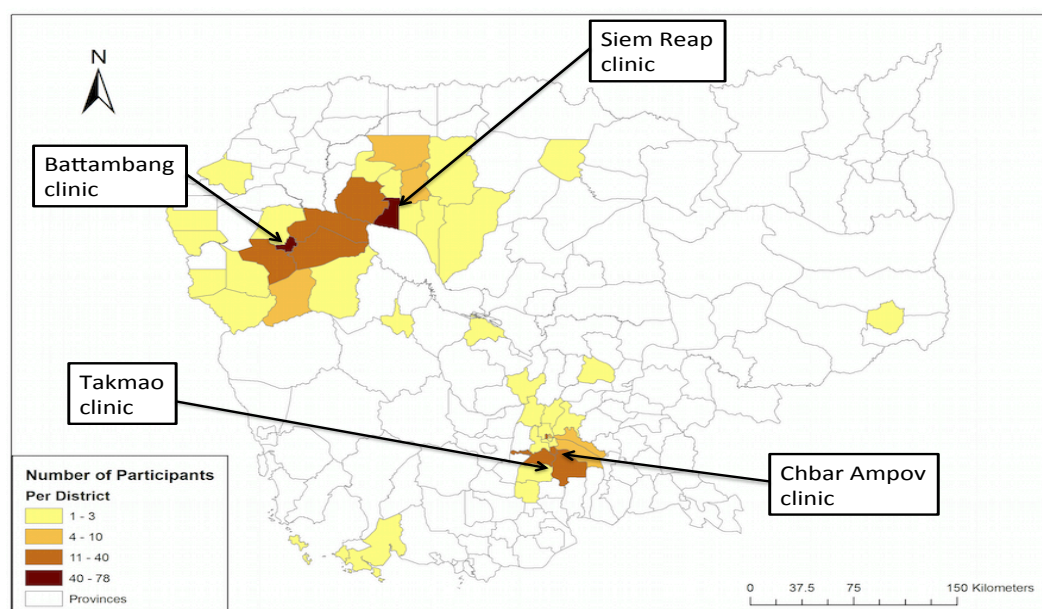
These data suggest that the trial findings are likely to be generalisable to MSI clinics. However, it is unclear if the trial findings are generalisable to other settings where women seek abortion services in Cambodia given that there are differences in background characteristics in women seeking abortions in different settings. Further research is recommended prior to implementing similar interventions in different settings.

Geographic location of trial participants

Figure 50 shows the geographical location of trial participants according to district in Cambodia and is shown primarily for interest. It was created using Geographic Information System (GIS) Software using Cambodia census data and data collected on participants' residence collected at baseline. Denser colours indicate increased

numbers of participants living in a particular district. It can be observed that participants are more geographically dispersed if recruited from the clinics serving rural areas (Battambang and Siem Reap) if compared to the peri-urban clinics.

Figure 50: Location of trial participants



Acknowledgement to Andrew Shantz for helping to produce this figure

Conclusions

As previously reported, at four months the intervention was associated with increased use of effective contraception (RR 1.39 (1.17-1.66)) and long-acting¹³ contraception (RR 3.35 (2.07-5.40)).(203) The analysis in this section suggests that the main contributing factor towards this finding was the choice of contraceptive method rather than use of any method, in particular increased initiation of intrauterine device and implant during the first four weeks post-abortion amongst women receiving the intervention (RR 3.05 (1.90-4.88)). In addition there was some evidence of reduced discontinuation of effective methods (HR 0.45 (0.20-1.01)), due to trends towards reduced method specific discontinuation and safe-method switching in the intervention group.

¹³ Intrauterine device, implant or permanent method

As previously reported, at 12 months, the intervention was *not* associated with increased use of effective contraception (RR 1.16 (0.92-1.47) but was associated with increased use of long-acting contraception (RR 2.08 (1.27-3.42)).(203) The analysis in this section suggests that the main contributing factor towards this was the aforementioned increased initiation of intrauterine device and implant during the first four weeks post-abortion amongst women receiving the intervention followed by increased discontinuation of short-acting methods overall; and less of a trend towards safe-switching in the intervention group. Hence the risk ratio for long-acting contraception use remained statistically significant whilst the risk ratio for overall effective contraception use reduced and lost statistical significance.

Overall discontinuation at 12 months was higher for short-acting methods, consistent with the literature.(16) There was a trend towards increased OC discontinuation in the intervention group and increased injectable discontinuation in the control group at four and 12 months. There was a trend towards increased safe-method switching after discontinuing a method amongst women receiving the intervention.

There was no evidence that the intervention effect at four-months varied amongst any subgroup apart from PAFP intentions at the time of seeking induced abortion services for unintended pregnancy. The study population appeared to be representative of MSI clients seeking abortion services at the four study clinics during 2013 in terms of baseline characteristics and PAFP use at two weeks.

Implications of these additional pre-specified and exploratory analyses will be discussed further in Chapter 8.

5.7 Assessing the validity and reliability of self-report data

Background

Contraception use can be measured for different reasons, for example to collect information on general patterns of contraception use over several years using Demographic and Health Surveys, or to assess the impact of interventions to improve contraception use, often focusing on specific methods, over a shorter time period. A variety of different approaches to measuring contraceptive use have been used or proposed, either to assess current use or adherence over time, using subjective or objective measures. This paper reports an overview of approaches to measuring adherence to the oral contraceptive (OC), intra-uterine device (IUD), sub-dermal implant, and injectable and describes how we assessed contraception use in the MOBILE Technology for Improved Family Planning (MOTIF) trial in Cambodia.(203)

Main text

Overview of measuring adherence to common contraceptive methods

The majority of studies assessing contraception use have relied on self-report measures, which are relatively simple and inexpensive to administer. However, concerns about bias associated with self-report measures leading to overestimation of contraceptive use and underestimation of abortion have led to calls for increased rigor in measuring contraception use.(188)(216)(217)

For fertility surveys, contraceptive calendars, such as those used in Demographic and Health surveys, have been found to generate more complete and accurate data on past self-reported contraceptive use than other questionnaire formats.(218)(219)(220) These methods are convenient, inexpensive to administer and the only practical way to obtain information on contraceptive use dating back several years. However, in

clinical trials, objective measures are generally considered preferable to subjective measures, as they are less prone to bias.(169) Table 25 summarises approaches to measuring use of different contraceptive methods.

Table 25: Summary of approaches to measuring adherence to different contraceptive methods

Contraceptive method	Measurement approach	Advantages	Disadvantages
Oral Contraceptive	Direct observation (clinician observes ingestion of pill)	Accurate and equates to ingestion	Impractical
	Self-reports (self-completed or interview administered questionnaire)	Simple, inexpensive and easy to administer.	Requires training for administrators. Subject to recall and social desirability bias.
	Clinic / pharmacy records	Can help to correct poor recall. Simple, inexpensive and objective. Usually easy to obtain data. Can measure at more than one point in time.	Does not equate to ingestion and requires a closed pharmacy system
	Pill counts (individual pill or pill pack counts)	Objective; quantifiable and easy to perform.	However, easily altered by participant (e.g. pill dumping), cannot assess timing of use
	Electronic Monitoring Devices	Objective, precise, tracks patterns of use over time.	Potentially expensive and may require return visits to download data. Participants may not adhere to using device, intervention might improve use of device rather than pill-taking behaviour.
	Blood hepatic binding globulin levels (Corticosteroid Binding Globulin, Thyroxine Binding Globulin, Lutenizing Hormone and Sex Hormone Binding Globulin)	Objective. Can distinguish between consistent use and non-use (Corticosteroid Binding Globulin and Thyroxine Binding Globulin more discriminating). Inexpensive compared to measuring contraceptive steroid level	Requires specialist laboratory. Can't distinguish between consistent and inconsistent users
IUD / implant	Blood contraceptive steroid level (e.g. Levonorgestrel or Ethinylestradiol)	Objective, indicates indigestion.	Difficult test, expensive therefore limited potential for replication in other studies, requires a blood test, will not distinguish consistent from inconsistent users
	Self-report	Simple, inexpensive and	Subject to recall bias and

	Clinical examination or ultrasound	easy to administer. Simple, inexpensive and easy to administer.	social desirability bias Intrusive, has to be performed in clinic setting, requires skilled personnel/ equipment
	Clinic or client record	Objective	Requires a closed pharmacy system. Self-held record can get lost
Injection	Self-report	Simple, inexpensive and easy to administer.	Subject to recall bias and social desirability bias.
	Clinic or clinic record	Objective and indicates current use	Requires a closed pharmacy system. Self-held record can get lost

The oral contraceptive is probably the most challenging contraceptive method to measure. The combined oral contraceptive pill (COCP) containing oestrogen and a progestogen is taken for 21 days, with a 7-day break, whereas the progesterone-only pill (POP) containing one hormone is taken continuously. One-year pregnancy rates are estimated to be 0.3% with perfect use, but 7-8% as commonly used,(6) thus measures that assess missed pills as well as current use are important.

No gold standard measure of OC use is available. The ideal measure of OC would be one that is objective, can distinguish reliably between non-users, inconsistent, and consistent users, does not rely on a closed pharmacy system (i.e. accounts for people obtaining contraception in different settings); is inexpensive, feasible in different settings, is acceptable to participants, and is applicable to pills containing different hormones. A systematic review of measurement methods for OC use found that the majority (71%) of research studies relied solely on self-report measures (such as interviewer or self-administered questionnaires) rather than objective measures, and the terminology used to describe OC use (such as “continuation”, “compliance” and “adherence”) varied and was rarely described.(189)

Objective measures of OC use include biological markers or electronic medication monitors. Biomarkers can either directly measure the hormones in the pill or a proxy

measure. Direct measurement of contraceptive steroid levels (for example, Ethinylestradiol or Levonorgestrel) is possible, but only at specialist laboratories, and thus for cost and logistical reasons, might not be feasible in low-income settings. Other researchers have proposed measurement of hepatic binding globulins, which are increased by Ethinylestradiol (EE2). Thyroxine Binding Globulin (TBG) and Corticosteroid Binding Globulin (CBG) were found to distinguish noncompliant users from compliant users.(221) In one study, riboflavin was added to the OC as a urinary marker and assessed by urine fluorescence.(222) However, the addition of a urine marker to a pill would present significant challenges, and requires a closed pharmacy system. The main advantage of biological measures is that they indicate ingestion of the pill and are good at assessing current use. However, disadvantages are that they are less good at distinguishing inconsistent users from consistent users,(214)(189) and blood tests may not be acceptable to study participants. It is theoretically possible to measure EE2 in urine samples by enzyme-linked immunosorbent assay (ELISA), an assay developed for detecting EE2 in animals for the food industry. This might be more acceptable than a blood test, but to our knowledge this test has not been validated for human urine.

Electric monitoring devices (EMDs) can be used to measure adherence to oral medication by recording when a participant opens a pill box or blister pack. Such information can be downloaded periodically or transmitted in real-time. EMDs have been shown to be more accurate than self-report measures, pill counts, and biomarkers for examining antidepressant adherence,(223) and used in low income settings, for example to assess anti-retroviral adherence in Kenya.(132) In the field of contraception, two studies reported poorer OC adherence as measured by electronic

medication monitoring compared with self-report measures.(214)(143) Thus, advantages of EMDs are that they can provide more detailed information of patterns of use over a period of time compared with self-report. Limitations of EMDs are that it can be difficult to distinguish whether interventions improve pill-taking behaviour or simply improve use of the monitor, that opening the container doesn't equate to ingestion, and the devices themselves could interfere with the intervention if the participant has to transfer pills into a container. Devices that mimic pill packets would be costly and require a closed pharmacy system.

Measuring use of other contraceptive methods such as implant, IUD and injectable are somewhat easier compared to OC as it is not necessary to assess daily adherence; the women is either protected from pregnancy by the method, or not. These methods can be assessed as follows. First, by self-report (i.e. asking the participant if they are using a method) but this method is subject to biases already mentioned. In particular it might be difficult to recall the date the method was started e.g. date of injection. Second, objectively by reviewing clinic records, but in the case of implant and IUD, this does not indicate continued use if the participant had the device removed in a different clinic. Finally, current use of IUD or implant can be assessed by clinical examination; by palpating the sub-dermal implant or visualising the IUD threads but this entails an intimate examination. IUD or implant use could also be assessed by ultrasound examination.

Assessing contraception use in the MOTIF trial

For the MOTIF trial, we did not consider it feasible to measure objective contraception use for several reasons. We were concerned that participants wouldn't be able to return to the clinic for objective follow-up due to lack of time as many lived in rural

areas far from the clinic. Furthermore we were concerned about whether it was appropriate, potentially a betrayal of trust, to ask women to return to clinic for internal examination to check IUD threads simply to verify self-report information already provided. We were not able to rely on clinic records of contraception use as the trial was not operating within a closed pharmacy system; oral and injectable contraceptives can be obtained from pharmacists without prescriptions in Cambodia, and long-acting reversible methods (intrauterine device or implant) could be removed in other clinics. Therefore assessment of the primary outcome, use of effective contraception at four and 12 months post-abortion for the MOTIF trial was self-report by phone call. The questionnaire was designed to reduce social desirability bias by first asking participants *"Are you using a contraception method?"* followed by *"Which method are you using?"* if the women answered *"Yes"* (without prompting for specific methods). We felt it was unlikely that participants would over-report using one particular contraception method over another e.g. IUD vs. implant. To assess reliability of self-report data we compared calendar data collected on effective contraception use at months 1-4 post-abortion, collected separately at four and 12 months. Agreement ranged from 80-84% with a kappa statistic ranging from 0.59 to 0.67 indicating fair to good agreement.

We aimed to assess the validity of the four-month data with 50 participants, calculating the sensitivity and specificity of self-reported data compared with objective measurement (considered the gold standard).⁽¹⁶⁷⁾ Consecutive participants recruited from the two peri-urban clinics who had provided self-report follow up were invited to attend for objective assessment of contraceptive use by a research assistant blinded to treatment allocation as follows: assess the position of an implant or IUD (ultrasound or

clinical examination according to participant preference); self-held record of injection within the previous three months or permanent method; pill counts defined as >90% of pills taken since last prescription dispensed. Those attending were given USD\$4 for travel expenses. In order to achieve our target of 50 face-to-face objective measurements we attempted to contact 94 participants of contraception use; thus achieving a 53% follow up rate (compared to self-report follow up of 86% at four months). We were unable to contact 18 participants. 20 participants declined to attend (the most common reason stated was lack of time). Six participants agreed, but then did not attend. We obtained valid measurements in 46 of 50 participants who attended. Three participants did not bring OC with them and one was ineligible as she had not provided self-reported contraception data. Amongst these 46 participants, the sensitivity and specificity was 100% for self-reported IUD, implant, injectable and OC use compared to objective measurement (Table 26).

Table 26: Objective vs. self-report follow up at four months

	Self-report (number)	Objective measurement (number)
Current contraception use		
IUD	11	11
Implant	4	4
Injectable	3	3
Oral contraceptive	9	9
No method/non-effective method	19	19
Total effective	27	27
Total no/non-effective method	19	19
Total measurements included in analysis	46	46

Amongst the 46 participants the sensitivity of self-report data compared to objective measurement (gold standard) was 100% (27/27*100) and the specificity was 100% (19/19*100)

It is uncertain if this validity study was helpful. Whilst the sensitivity and specificity of objectively measured contraception was 100% in those attending follow-up, the response rate was low and it is not clear that those who attended were representative

of the wider study population. For example, if a participant provided inaccurate self-report data, they might be less likely to attend for objective assessment.

Conclusion

In the MOTIF trial, use of self-report measures resulted in higher rates of follow up compared to attempts at objective measures. Self-report measures showed fair/good reliability and the validity study did not identify any cases of misclassification.

However, the method for verifying self-reported OC use by pill counts was also prone to detection bias.

There is no perfect method of assessing contraception use and researchers designing future studies should give consideration of what to measure, for example current use or detailed patterns of use over time, and remain mindful of what will be feasible and acceptable to the study population. For OC use, researchers should consider using the definitions of 'continuation', 'discontinuation', 'interrupted use' and 'missed pills' as recommended by Hall et al.(189)

Objective measures using clinic records or electronic medication monitors might be possible if there is a closed pharmacy system. EMDs linked to mobile devices providing real-time data on pill taking will provide the most detailed information on OC use.

Biological measures or clinical examination might be feasible if participants are willing and able to return to the clinic, and there is laboratory capacity. Self-report measures can be optimised by careful consideration of questions to avoid response-style bias.

Although self-reported data on contraception use are considered less reliable, and prone to social desirability bias, it is often the standard approach for contraception research and provides data comparable to previous studies. (188)(189) A validity study could be considered to verify self-report measures. Future research could explore the

possibility of a urine EE2 assay as an alternative to a blood test to distinguish between users and non-users of OC.

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5.8 Assessing loss to follow up in the MOBILE Technology for Improved Family Planning (MOTIF) trial

Background

Loss to follow-up (LTFU) in clinical trials is an important source of bias that can affect statistical power and generalisability of findings and trials with large LTFU can be downgraded in systematic reviews. Systemic differences in LTFU between groups can result in attrition bias.(169)

Successful follow up requires participants to be found, and also willing to participate with the data collection procedure.(224) LTFU can be classified as missing at random (MAR) or not missing at random (NMAR), for example increased attrition in younger people. In this situation a complete case analysis, restricted to participants with available follow up data, may produce a biased estimation of the true effect. A common approach to dealing with missing outcome data is to impute outcomes and treat them as if they were real measurements, known as multiple imputation.(225)

The aim of this paper is to assess factors associated with LTFU in the MOBILE Technology for Improved Family Planning (MOTIF) trial in Cambodia and compare how the result might have varied using different analysis methods.

Main text

For the MOTIF trial, the primary outcome, self-reported use of an effective contraceptive, was assessed by attempting to contact participants by phone at four and 12-months. We used evidence-based methods to try and reduce the chance of LTFU such as collecting as many possible phone numbers on recruitment, including those of friends or family members, with consent of the participant.(226)(167) At the time of the trial few participants used email, there was not a functioning postal system

in rural areas in Cambodia, and we had limited resources to visit participants homes. At four months we obtained primary outcome data from 431 participants (86%). Amongst the 69 clients LTFU, six withdrew and we were unable to contact 63 participants. At 12 months we obtained primary outcome data from 328 participants (66%). Amongst the 172 clients LTFU, eight withdrew and RAs were unable to contact 164 participants.

For the primary analysis we undertook a complete case analysis, similar to the approach used in similar trials of interventions of interventions delivered by mobile phone to increase contraception use.⁽¹⁴³⁾⁽¹⁴²⁾ Using a complete case analysis the intervention increased self-reported use of an effective contraception method at four months post-abortion (64% vs. 46% risk ratio (RR) 1.39, 95% CI 1.17-1.66; $p < 0.001$), but not after 12 months (50% vs. 43% RR 1.16, 95% CI 0.92-1.47; $p = 0.208$).

Investigating missing data

Reasons, as documented by the research assistants, for LTFU at 12 months amongst these 164 participants were as follows: 76 (46%) times the phone was switched off, 57 (35%) times there was an automated response that the number not in use and not yet re-assigned, 16 (10%) times someone else answered the phone, 10 (6%) cases where the participant had moved abroad, 3 (2%) cases of an automated response that the phone couldn't receiving incoming calls, and 2 (1%) cases where the participant didn't want to talk.

We conducted an exploratory analysis to identify predictors of LTFU from the variables collected at trial recruitment to assess whether data were missing at random or not. To maximise statistical power, binary variables were created from some of the categorical variables. First we undertook univariable analysis to examine the crude

association between each baseline variable and LTFU. In the univariable analysis, age <25, lower socio-economic status (i.e. no access to motorised transport), not planning to use post-abortion contraception and not providing an additional friend/family contact number were associated with LTFU at four months. Age <25, lower socio-economic status and usually or sometimes having phone credit were associated with LTFU at 12 months. There was no evidence of differential LTFU between those assigned to the intervention or control at four or 12 months.

We then undertook multivariable analysis to explore the association between variables and LTFU, controlling for confounding, using logistic regression analysis. Age and socio-economic status are associated with contraception use and maybe associated with seeking LTFU. (74)(3) We therefore considered these variables as confounders in the analysis. In the multivariable analysis, aged <25, lower socio-economic status, not planning to use post-abortion contraception and not providing an additional friend/family contact number remained as predictors of LTFU at four months; LTFU was significantly increased amongst women aged <25 years compared to aged >25 (Odds Ratio (OR) 2.31; $p=0.002$), amongst women without access to motorised transport compared to women with access to motorised transport (adjusted OR 2.44; $p=0.008$), amongst women not planning to use post-abortion contraception compared to women planning to use (OR 2.34; $p=0.05$), and amongst women who didn't provide additional contact numbers compared to those that did (OR 2.40; $p=0.002$) (Table 27).

Table 27: Predictors of missing data at four months

	Followed up N=431	LTFU N=69	Crude OR	p value	Adjusted OR	p value
Age group						
Age >25 (r)	306 (89%)	37 (11%)	1.00			
Age <25	125 (80%)	32 (20%)	2.12 (1.26-3.55)	0.004	2.31 (1.36-3.92)	0.002
Residence						
Rural (r)	279 (87%)	42 (13%)	1.00			
Urban	152 (85%)	27 (15%)	1.18 (0.70-1.99)	0.535	1.11 (0.65-1.90)	0.699
Socio-economic status						
Access to motorised transport (r)	381 (88%)	54 (12%)	1.00			
No access to motorised transport	50 (77%)	15 (23%)	2.12 (1.11-4.03)	0.022	2.44 (1.26-4.72)	0.008
Education						
Secondary or above (r)	263 (87%)	41 (13%)	1.00			
None or primary	168 (86%)	28 (14%)	1.07 (0.64-1.79)	0.800	1.14 (0.64-2.02)	0.665
Marital status						
Married/living together (r)	403 (87%)	61 (13%)	1.00			
Never married or living together	23 (79%)	6 (21%)	1.72 (0.67-4.40)	0.255	1.32 (0.51-3.43)	0.573
Divorced/separated	5 (71%)	2 (29%)	2.64 (0.50-13.92)	0.252	1.31 (0.22-7.75)	0.769
# living children						
1 or more (r)	312 (88%)	41 (12%)	1.00			
0	119 (81%)	28 (19%)	1.79 (1.06-3.03)	0.030	1.31 (0.71-2.42)	0.382
# previous abortions						
0 (r)	254 (85%)	45 (15%)	1.00			
1 or more	177 (88%)	24 (12%)	0.77 (0.45-1.30)	0.324	0.91 (0.52-1.57)	0.724
Contraception decision-making						
Joint decision (r)	257 (89%)	33 (11%)	1.00			
Mainly participant	79 (82%)	17 (18%)	1.68 (0.89-3.17)	0.112	1.76 (0.91-3.37)	0.091
Mainly husband/partner	66 (85%)	12 (15%)	1.42 (0.69-2.89)	0.340	1.58 (0.76-3.26)	0.220
Mobile phone access						
Never shares (r)	225 (87%)	34 (13%)	1.00			
Shares	206 (85%)	35 (15%)	1.12 (0.68-1.87)	0.651	1.21 (0.72-2.03)	0.474
Disclosure of abortion to others						
Yes (r)	174 (85%)	30 (15%)	1.00			
No	32 (86%)	5 (14%)	0.91 (0.33-2.51)	0.850	1.10 (0.39-3.16)	0.853
PAFP intentions						
Yes (r)	166 (89%)	21 (11%)	1.00			
No	31 (74%)	11 (26%)	2.80 (1.23-6.39)	0.014	2.34 (1.00-5.46)	0.050
Undecided	234 (86%)	37 (14%)	1.25 (0.71-2.21)	0.444	1.13 (0.63-2.01)	0.689
Fertility plans						
No more/none (r)	123 (88%)	16 (12%)	1.00			
Have a/another child	261 (85%)	47 (15%)	1.38 (0.75-2.54)	0.293	1.00 (0.50-1.96)	0.990
Undecided	47 (89%)	6 (11%)	0.98 (0.36-2.66)	0.971	0.88 (0.32-2.45)	0.810
Abortion method						
Medical (r)	178 (86%)	29 (14%)	1.00			
Surgical	253 (86%)	40 (14%)	0.97 (0.58-1.62)	0.909	1.00 (0.59-1.70)	0.990
Phone credit						
Always (r)	158 (88%)	21 (12%)	1.00			

Usually	102 (80%)	26 (20%)	1.92 (1.02-3.59)	0.042	1.71 (0.90-3.24)	0.101
Sometimes	171 (89%)	22 (11%)	0.97 (0.51-1.83)	0.920	0.88 (0.45-1.71)	0.705
Friend/family contact provided						
Yes (r)	338 (88%)	44 (12%)	1.00			
No	93 (79%)	25 (21%)	2.07 (1.20-3.55)	0.009	2.40 (1.37-4.21)	0.002
# phone numbers provided						
Two or more (r)	128 (89%)	16 (11%)	1.00			
One	303 (85%)	53 (15%)	1.40 (0.77-2.54)	0.269	1.42 (0.77-2.59)	0.261
Randomisation						
Intervention (r)	211 (85%)	38 (15%)	1.00			
Control	220 (88%)	31 (12%)	0.78 (0.47-1.30)	0.346	0.81 (0.48-1.37)	0.431

*Adjusted for age and SES. P values less than 0.05 were regarded as being significant. Analyses were undertaken using STATA 13.1.

At 12 months, aged <25, lower socio-economic status and phone credit remained as predictors of LTFU; LTFU was significantly increased amongst women aged <25 years compared to aged >25 (OR 1.59; p=0.023), amongst women without access to motorised transport compared to women with access to motorised transport (OR 2.04; p=0.009), and amongst women who usually (OR 1.85; p=0.014) or sometimes (OR 1.59; p=0.046) have phone credit compared to women who always have phone credit (Table 28).

Table 28: Predictors of missing data at 12 months

	Followed up N=328	LTFU N=172	Crude OR	p value	Adjusted OR	p value
Age group						
Age >25 (r)	235 (69%)	108 (31%)	1.00			
Age <25	93 (59%)	64 (41%)	1.50 (1.01-2.21)	0.043	1.59 (1.07-2.36)	0.023
Residence						
Rural (r)	212 (66%)	109 (34%)	1.00			
Urban	116 (65%)	63 (35%)	1.06 (0.72-1.55)	0.780	1.04 (0.70-1.54)	0.848
Socio-economic status						
Access to motorised transport (r)	294 (68%)	141 (32%)	1.00			
No access to motorised transport	34 (52%)	31 (48%)	1.90 (1.12-3.22)	0.017	2.04 (1.19-3.47)	0.009
Education						
Secondary or above (r)	209 (69%)	95 (31%)	1.00			
None or primary	119 (61%)	77 (39%)	1.42 (0.98-2.07)	0.065	1.48 (0.98-2.23)	0.060
Marital status						
Married/living together (r)	309 (67%)	155 (33%)	1.00			
Never married or living together	16 (55%)	13 (45%)	1.62 (0.76-3.45)	0.212	1.38 (0.64-2.99)	0.416
Divorced/separated	3 (43%)	4 (57%)	2.66 (0.59-12.02)	0.204	1.51 (0.31-7.41)	0.613
# living children						

1 or more (r)	241 (68%)	112 (32%)	1.00			
0	87 (59%)	60 (41%)	1.48 (1.00-2.21)	0.052	1.29 (0.81-2.04)	0.280
# previous abortions						
0 (r)	201 (67%)	98 (33%)	1.00			
1 or more	127 (63%)	74 (37%)	1.20 (0.82-1.74)	0.351	1.34 (0.91-1.98)	0.136
Contraception decision-making						
Joint decision (r)	193 (67%)	97 (33%)	1.00			
Mainly participant	63 (66%)	33 (34%)	1.04 (0.64-1.70)	0.868	1.06 (0.65-1.74)	0.812
Mainly husband/partner	53 (68%)	25 (32%)	0.94 (0.55-1.60)	0.816	0.99 (0.57-1.69)	0.959
Mobile phone access						
Never shares (r)	175 (68%)	84 (32%)	1.00			
Shares	153 (63%)	88 (37%)	1.20 (0.83-1.73)	0.337	1.25 (0.86-1.81)	0.252
Disclosure of abortion to others						
Yes (r)	134 (66%)	70 (34%)	1.00			
No	19 (51%)	18 (49%)	1.81 (0.89-3.68)	0.099	1.97 (0.96-4.05)	0.066
PAFP intentions						
Undecided (r)	181 (67%)	90 (33%)	1.00			
Yes	120 (64%)	67 (36%)	1.12 (0.76-1.66)	0.562	1.20 (0.81-1.79)	0.360
No	27 (64%)	15 (36%)	1.12 (0.57-2.21)	0.749	1.05 (0.53-2.10)	0.886
Fertility plans						
No more/none (r)	90 (65%)	49 (35%)	1.00			
Have a/another child	197 (64%)	111 (36%)	1.03 (0.68-1.57)	0.872	0.87 (0.55-1.38)	0.561
Undecided	41 (77%)	12 (23%)	0.54 (0.26-1.12)	0.096	0.51 (0.24-1.08)	0.080
Abortion method						
Medical (r)	138 (67%)	69 (33%)	1.00			
Surgical	190 (65%)	103 (35%)	1.08 (0.74-1.58)	0.673	1.09 (0.74-1.60)	0.651
Phone credit						
Always (r)	132 (74%)	47 (26%)	1.00			
Usually	75 (59%)	53 (41%)	1.98 (1.22-3.22)	0.006	1.85 (1.13-3.02)	0.014
Sometimes	121 (63%)	72 (37%)	1.67 (1.07-2.60)	0.023	1.59 (1.01-2.51)	0.046
Friend/family contact provided						
Yes (r)	250 (65%)	132 (35%)	1.00			
No	78 (66%)	40 (34%)	0.97 (0.63-1.50)	0.896	1.03 (0.66-1.60)	0.897
# phone numbers provided						
Two or more (r)	99 (69%)	45 (31%)	1.00			
One	229 (64%)	127 (36%)	1.22 (0.81-1.85)	0.346	1.22 (0.80-1.85)	0.357
Randomisation						
Intervention (r)	169 (68%)	80 (32%)	1.00			
Control	159 (63%)	92 (37%)	1.22 (0.84-1.77)	0.287	1.25 (0.86-1.81)	0.253

*Adjusted for age and SES. P values less than 0.05 were regarded as being significant. Analyses were undertaken using STATA 13.1.

We then undertook two different analyses to compare with the complete case analysis. First, we undertook multiple imputation to estimate the effect of the intervention on the primary outcome at four and 12 months. This involved replacing each missing primary outcome value with a plausible imputation based on the

characteristics of missing values observed. *Logistic regression with predictor variables age group, socioeconomic status, PAFP intentions and whether an additional friend or family contact was provided was used for univariate imputation of the outcome at four months and predictor variables age group, socioeconomic status and phone credit for imputation of the outcome at 12 months. Multiple imputation was conducted separately for the outcome at 4 and 12 months with 100 imputed datasets created for each outcome respectively.* Using MI, the intervention also showed an effect at four months (63% vs. 45%; risk ratio (RR) 1.42, 95% CI 1.19-1.69; $p=0.001$), but not after 12 months (48% vs. 43%; RR 1.12, 95% CI 0.89-1.40; $p=0.349$). Second, we conducted sensitivity analyses treating all participants LTFU as non-users of contraception (extreme case scenario) to estimate the effect of the intervention on the primary outcome at 4 and 12 months.(213) In this analysis self-reported effective contraception use also remained significantly increased when we considered participants LTFU as non-users at four months (54% vs. 40%; RR 1.35, 95% CI 1.12-1.63; $p=0.002$) but not at 12 months (34% vs. 27%; RR 1.25, 95% CI 0.95-1.63; $p=0.106$). Table 29 shows how the effect measure varies according to the analysis method used. Using MI, the risk ratio was slightly increased at four and slightly decreased at 12 months compared to the complete case analysis.

When counting all participants LTFU as non-users of contraception the risk ratio was slightly decreased at four months and slightly increased at 12 months, compared to the complete case analysis. Despite the changes in the risk ratio, use of the different analysis methods did not result in an effect becoming statistically significant, or vice versa.

Table 29: Effect measure variation according to the analysis method used

	Intervention group number (%)	Control group number (%)	RR (95% CI)	p value	Intervention group number (%)	Control group number (%)	RR (95% CI)	p value
		Four months				12 months		
Complete case analysis	135/211 (64%)	101/220 (46%)	1.39 (1.17 – 1.66)	<0.001	84/169 (50%)	68/159 (43%)	1.16 (0.92 – 1.47)	0.208
Counting participants LTFU as non-users	135/249 (54%)	101/251 (40%)	1.35 (1.12 – 1.63)	0.002	84/249 (34%)	68/251 (27%)	1.25 (0.95 – 1.63)	0.106
Multiple imputation	158/249 (63%)	114/251 (45%)	1.42 (1.19– 1.69)	0.000	120/249 (48%)	108/251 (43%)	1.12 (0.89– 1.40)	0.349

Conclusions

Factors associated with LTFU in the MOTIF trial were young age, lower SES, not planning to use post-abortion contraception, phone credit and not providing additional contact numbers. Reasons for LTFU amongst younger women might be that they changed phone number (couldn't be found) or perhaps due to potential stigma of contraception use in young people (no longer wanted to participate in the trial). Younger participants were also found to be at increased risk of LTFU in a head injury trial.(224) LTFU amongst women of lower SES might be due to changing phone number or no longer having access to a phone. Women not planning to use contraception might have been less motivated to participate in the trial follow up. The finding that LTFU was increased in those not providing multiple contacts is consistent with existing evidence.(226) Although the risk ratio showed slight variation using multiple imputation and counting those LTFU as non-users, there was no significant change in the principal findings.

Future studies assessing contraception use might anticipate increased attrition amongst younger participants and those of lower SES or who do not provide additional

contact details. Attrition could be reduced by collecting as many contact details as possible, providing incentives, and possibly enhanced counselling to groups at higher risk of LTFU on recruitment.(226) Multiple imputation should be considered in addition to complete case analysis if LTFU not missing at random is expected or observed.

6. Process Evaluation of a Mobile Phone-Based Intervention to Support Post-Abortion Contraception in Cambodia

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS

SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	N/A		
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	N/A	Was the work subject to academic peer review?	

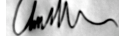
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Reproductive Health Journal
Please list the paper's authors in the intended authorship order:	Chris Smith ¹ (corresponding author), Sokhey Ly ² , Vannak Uk ² , Ruby Warnock ³ , Phil Edwards ¹ , Caroline Free ¹ ¹ Department of Population Health, London School of Hygiene and Tropical Medicine, Keppel Street, London, WC1E 7HT, UK ² Marie Stopes International, Phnom Penh, Cambodia ³ Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, USA
Stage of publication	Submitted to journal on 12 th August 2016 (editor assigned)

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the first author on this paper. I was responsible for designing the paper, conducting the statistical analysis drafting the manuscript. My co-authors supported this work in an advisory capacity and helped to edit the writing.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

Chapter transition notes

The trial results and additional analyses (Chapter 5) comprised analysis of trial follow up data reporting the overall effect of the intervention, but provide limited insights into the mechanism of action and how the intervention was perceived by women. Chapters 6 and 7 report the process evaluation. This chapter (Chapter 6) is a quantitative study to assess participants' interaction with the intervention from a service provider perspective. Chapter 7 is a qualitative study which seeks to gain insights into how the intervention was perceived by women.

Process Evaluation of a Mobile Phone-Based Intervention to Support Post-Abortion Contraception in Cambodia

6.1 Abstract

Background

The MOBILE Technology for Improved Family Planning (MOTIF) trial assessed a mobile phone-based intervention comprising voice messages and counsellor support to increase post-abortion contraception at four Marie Stopes International clinics in Cambodia. The aim of this process evaluation was to assess participants' interaction with the intervention from a service provider perspective.

Methods

(1) We conducted a descriptive analysis to assess participants' interaction with the intervention. (2) In order to explore how the intervention might work, we assessed associations between interaction with the intervention and contraception use using logistic regression analysis. (3) We undertook a logistic regression analysis to assess associations between baseline socio-demographic factors and *ever* requesting to speak to a counsellor (pressing '1'), a variable found to be associated with contraception use.

Results

Amongst 249 women that received six interactive voice messages +/- counsellor support for contraception, around half actively requested to speak to a counsellor (pressed '1') and over 90% spoke to a counsellor at some stage. Women who spoke to the counsellor having requested to (by pressing '1') were more than four times as likely to be using effective contraception at four months compared to women who didn't request or speak to the counsellor (Odds Ratio 4.39; 95% CI: 1.15-16.71). There was a small, non-statistically significant increase in contraception use amongst women

that spoke to the counsellor without requesting a call. Increased parity, a history of >2 previous induced abortions, lower socio-economic status, and medical abortion (after adjusting for age, socio-economic status and residence) were associated with requesting to speak to a counsellor.

Conclusions

The interactive message can identify a subgroup of women in whom counselling will be more effective and appears to be equitable in terms of engaging those most in-need. The intervention could be adapted based on the findings of this study.

6.2 Introduction

The past decade has seen rapid expansion in delivery of health-care interventions by mobile phone ('mHealth').(112) In the field of contraception, mobile phone-based interventions have been developed to support uptake of methods or reduce discontinuation, for example by providing reminders, or support for clients experiencing side-effects.(227) However, the effects of interventions delivered by mobile phone for improving contraception use have not been reliably established.(227)

Our trial, MObile Technology for Improved Family Planning (MOTIF), randomised 500 women seeking elective induced abortion services aged 18 years or older to a personalised mobile phone-based behaviour change intervention or to a control group. The trial results and a detailed description of the intervention and its development are reported elsewhere.(203)(212) In brief, the intervention comprised a series of automated interactive 'real-time' voice messages over the three-month post-abortion period in addition to standard care. Women would receive the first message within one week of attending the clinic, and then every two weeks, with a total of six

messages. The message was designed to remind women about contraception methods available to them and provide a conduit for additional support.(167) Women could press '1' to request to speak to a counsellor, press '2' if they did not require a call back, or press '3' to opt-out of receiving further messages. Women who pressed '1', or who did not respond, received a phone call from a counsellor. The phone calls provided individualised counselling intending to encourage contraception use by reminding women about available methods and providing support for side-effects. Counsellors could make appointments for implant or intra-uterine device insertions or women could opt to receive additional oral contraceptive pill or injectable reminder messages. The counsellor could discuss contraception with the husband or partner, if the woman requested or women could call in to the service to request to speak with a counsellor. The intervention increased self-reported use of an effective contraception method at four months post-abortion (135/211 (64.0%) vs. 101/220 (45.9%) risk ratio (RR) 1.39, 95% CI 1.17-1.66; $p < 0.001$), but not after 12 months (84/ (49.7%) vs. 68/ (42.8%) RR 1.16, 95% CI 0.92-1.47; $p = 0.208$). However, self-reported long-acting contraception use (intrauterine device, implant or permanent method) was increased at four and 12 months.(203)

As a complex intervention delivered by automated voice messages and phone counselling, it is not clear what components of the intervention resulted in behaviour change. Our intervention was based on literature on the determinants of contraceptive use and a similar approach to Lester (2010) who hypothesized that regular structured mobile phone-based support could improve HIV medication adherence.(127)(212) However, for research conducted in 'real-life' settings, it cannot be assumed that the delivery of a complex intervention will be exactly as planned in

the design stage of a trial. Process evaluation of randomised controlled trials can lead to a greater understanding of what works, and provide meaningful interpretation of the effects on an intervention to inform future implementation.(228)(201) In a subsequent paper we will report findings from interviews conducted with participants that received the intervention. The aim of this study was to assess participants' interaction with the intervention from a service provider perspective and to consider how the intervention could be improved. Specific objectives were to:

1. Describe the response to voice messages and number of counsellor contacts over the intervention duration
2. Examine associations between interaction with the intervention and subsequent contraception use
3. Assess associations between baseline socio-demographic factors and interaction with the intervention

6.3 Methods

This quantitative study used data collected during the intervention and trial. First, we undertook a descriptive analysis to assess how participants interacted with the intervention. Counsellors delivering the intervention made a record of all mobile phone communications with participants. We report the response to voice messages, the number and type of counsellor contacts and number of women that opted out of the intervention or that the counsellor was unable to contact using descriptive statistics.

Second, in order to explore how the intervention might work, we assessed associations between interaction with the intervention and effective and long-acting contraception use using logistic regression analysis. Using data collected by counsellors delivering the

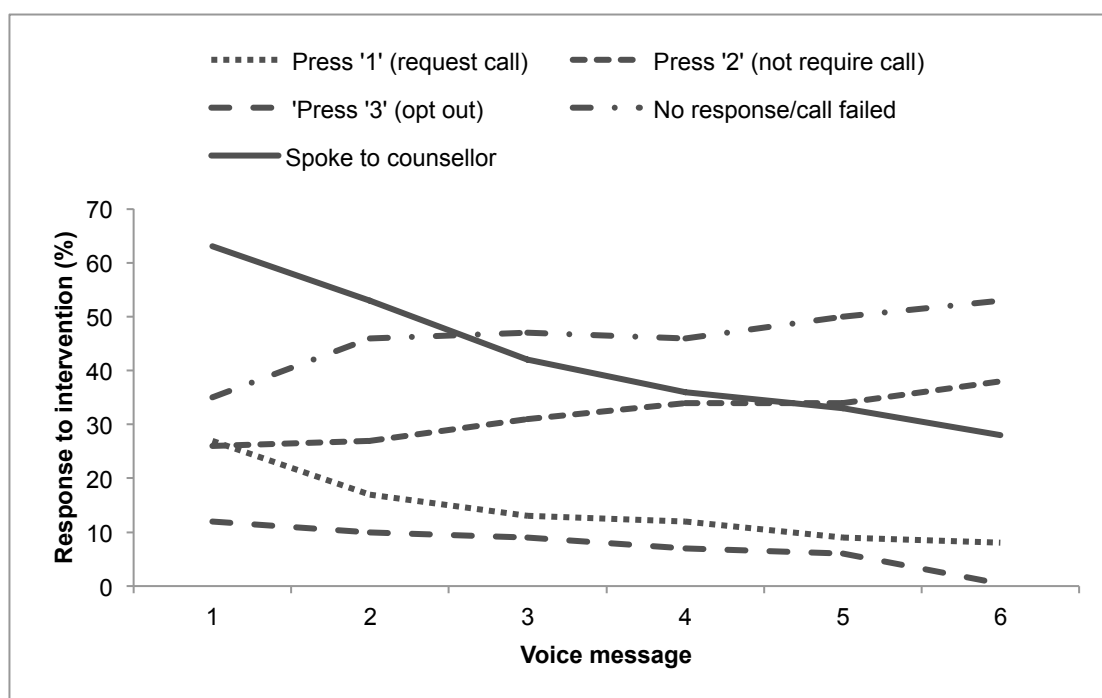
intervention we created variables based on response to the voice messages and whether women spoke to the counsellor or received pill or injection reminder messages. We conducted a pre-specified per-protocol analysis to assess the impact of the intervention among participants who responded to at least one voice message.⁽¹⁶⁷⁾ We estimated odds ratios (OR) with 95% confidence intervals (CI). Third, we undertook a logistic regression analysis to assess associations between baseline socio-demographic factors and *ever* requesting to speak to a counsellor (pressing '1'), a variable that was found to be associated with contraception use in the previous analysis. As the voice message stated "*Press 1 if you would like me to call you back to discuss contraception*" we considered plausible, 'a priori' confounders that might be associated with contraception use in Cambodia. Age, socio-economic status, residence, education and number of living children are associated with contraception use in Cambodia and were included in the adjusted analysis.⁽⁷⁷⁾⁽³⁾ As almost all the women in the trial (>99%) were able to recognise numbers on a phone and spoke Khmer as their mother tongue, we did not consider confounders that might be associated with the ability to understand or respond to a voice message. For categorical variables in the adjusted analysis, we assessed the statistical significance of the crude association, controlled for the effect of the confounding variables using the Likelihood ratio test. Ethical approval for the MOTIF study was obtained from ethics committees at the London School of Hygiene and Tropical Medicine and Marie Stopes International and the Cambodia Human Research ethics committee.

6.4 Results

1. Interaction with the intervention

Figure 51 shows the response to voice messages over time. The proportion of '1' responses (requesting a call) decreased from 27% at voice message one to 8% by message six.

Figure 51: Interaction with intervention over time



Overall, 49% of clients ever pressed '1' (to request to speak to the counsellor). The proportion of '2' responses (not requiring a call back) increased from 26% to 38%. The proportion of 'call failed' (no response to the voice message) increased from 35% to 53% at voice message six. The proportion of clients that spoke to a counsellor decreased from 64% at voice message one to 26% at voice message six. In total, there were 210 (15%) '1' responses, 452 (32%) '2' responses, 109 (8%) '3' responses, 657 (46%) 'no responses', 613 calls from the counsellor to client (outgoing) and approximately 100 calls from the client to the counsellor (data not systematically recorded). The mean number of outgoing phone calls per client was 2.46 (standard deviation 1.48). Overall, 92% of participants ever spoke to a counsellor. It is not clear

how often the counsellor discussed contraception with the women's husband or partner, as this information was not systematically recorded.

Twenty per cent (49/249) of participants receiving the intervention opted to receive oral contraceptive or injection reminders at some stage. Of the 24 women that received a reminder message three months after receiving the injectable, 83% (20/24) reported continued use at four-month follow up. Of the 25 women that received monthly oral contraceptive reminders, 68% (17/25) reported continued pill use at four-months.

By voice message six, 15 (6%) clients had opted out. Reported reasons according to the counsellors notes were that they were 'too busy' and had 'no time', or the 'phone was answered by someone else'. Six participants (2%) randomised to the intervention did not receive any messages; five due to non-functioning phone number and in one case someone not known to the participant answered the phone.

2. Association between interaction with the intervention and contraception use

Table 30 shows associations between interaction with the intervention and effective and long-acting contraception use at four months. The following factors were associated with effective contraception use at four months: Requesting to speak to a counsellor (pressing '1') compared to not pressing '1' after the first voice message (OR 3.37; 95% CI: 1.62-6.98); *ever* requesting to speak to a counsellor (pressing '1') compared to *never* requesting to speak to a counsellor (OR 2.51; 95% CI: 1.41-4.47); speaking to the counsellor having requested to (pressed '1') compared to *never* speaking and requesting to speak to the counsellor (OR 4.39; 95% CI: 1.15-16.71) or speaking to the counsellor having not requested to (OR 1.79; 95% CI 0.47-6.79);

received pill or injection reminder compared to not received a pill or injection reminder (OR 4.63; 95% CI: 2.11-10.16).

Table 30: Association between interaction with the intervention and effective and long-acting contraception use at 4 months

	Using effective contraception	OR	p value	Using long-acting contraception	OR	p value
	No/total no. of respondents (%)			No/total no. of respondents (%)		
Per-protocol analysis						
Responded to 1-2 voice messages (r)	33/55 (60%)	1.00		18/55 (33%)	1.00	
Responded to >2 voice messages	89/124 (72%)	1.70 (0.87-3.30)	0.121	40/124 (32%)	0.98 (0.50-1.93)	0.951
Response to voice message 1						
Call failed (r)	40/69 (58%)	1.00		16/69 (23%)	1.00	
1	49/60 (82%)	3.23 (1.44-7.26)	0.005	24/60 (40%)	2.21 (1.03-4.73)	0.041
2	36/58 (62%)	1.19 (0.58-2.42)	0.639	18/58 (31%)	1.49 (0.68-3.28)	0.321
3	10/24 (42%)	0.52 (0.20-1.33)	0.171	3/24 (12%)	0.47 (0.12-1.79)	0.271
Response to voice message 1						
Didn't press '1' (r)	86/151 (57%)	1.00		37/151 (25%)	1.00	
Pressed '1'	49/60 (82%)	3.37 (1.62-6.98)	0.001	24/60 (40%)	2.05 (1.09-3.88)	0.026
Whether participant ever pressed '1'						
Never (r)	53/100 (53%)	1.00		18/100 (18%)	1.00	
1 or more	82/111 (74%)	2.51 (1.41-4.47)	0.002	43/111 (39%)	2.88 (1.52-5.45)	0.001
Spoke to counsellor after voice message '1'						
No (r)	44/74 (59%)	1.00		20/74 (27%)	1.00	
Yes	91/137 (66%)	1.35 (0.75-2.42)	0.315	41/137 (30%)	1.15 (0.61-2.17)	0.658
Whether participant ever spoke to counsellor						
Never (r)	4/11 (36%)	1.00		1/11 (9%)	1.00	
1 or more	131/200 (66%)	3.32 (0.94-11.74)	0.062	60/200 (30%)	4.29 (0.54-34.23)	0.170
Whether pressed '1' if spoke to counsellor						
Spoke to counsellor & never pressed '1' (r)	49/90 (54%)	1.00		17/90 (19%)	1.00	
Spoke to counsellor & ever pressed '1'	82/110 (75%)	2.45 (1.35-4.45)	0.003	43/110 (39%)	2.76 (1.44-5.29)	0.002
Combinations of pressing '1' and speaking to counsellor						
Never pressed '1' & never spoke to counsellor (r)	4/10 (40%)	1.00		1/10 (10%)	1.00	
Never pressed '1' & spoke to	49/90 (54%)	1.79 (0.47-6.79)	0.390	17/90 (19%)	2.10 (0.25-17.68)	0.496

counsellor							
Pressed '1' & spoke to counsellor	82/110 (75%)	4.39 (1.15-16.71)	0.030	43/110 (39%)	5.78 (0.71-47.22)		0.102
Pressed '1' & never spoke to counsellor	0/1 (0%)	1.00 (-.)	.	0/1 (0%)	1.00 (-.)		.
Whether received pill or injection reminders							
Didn't receive pill or injection reminder (r)	96 (59%)	1.00		60 (37%)	1.00		
Received pill or injection reminder	39 (83%)	4.63 (2.11-10.16)	<0.001	1 (2%)	0.08 (0.01-0.62)		0.015
All participants	135/211 (64%)			61/211 (29%)			

The per-protocol analysis included 179 participants. Participants were categorised as 'highly protocol adherent' if they responded (i.e. pressed number '1' or '2') to more than three messages and 'less protocol adherent' if they responded to three or fewer messages

The following factors were associated with long-acting contraception use at four months: Requesting to speak to a counsellor (pressing '1') compared to not pressing '1' after the first voice message (OR 2.05; 95% CI: 1.09-3.88); *ever* compared to *never* requesting to speak to a counsellor (OR 2.88; 95% CI: 1.52-5.45); speaking to the counsellor and *ever* pressing '1' compared to speaking to the counsellor and *never* pressing '1' (OR 2.76; 95% CI: 1.44-5.29).

3. Association between baseline variables and response to the intervention

Table 31 shows the association between socio-demographic baseline variables and response to the intervention.

The following socio-demographic factors were associated with ever requesting to speak to the counsellor (pressing '1'): Age greater than 25 compared to less than 25 (unadjusted OR 1.78; 95% CI: 1.05-3.02) but not after adjusting for confounding variables; lower compared to higher socio-economic status (unadjusted OR 2.92; 95% CI: 1.23-6.90) which remained statistically significant; being married or living together compared to never married or living together (unadjusted OR 4.25; 95% CI: 1.17-15.46)

Table 31: Association between baseline variables and interaction with intervention

	Never pressed '1'	Ever pressed '1'	Crude OR	p value	Adjusted OR*	P value
	N=127	N=122				
Age group						
Age <25 (r)	53 (60%)	35 (40%)	1.00			
Age >25	74 (46%)	87 (54%)	1.78 (1.05-3.02)	0.032	1.06 (0.52-2.19)	0.864
Residence (urban/rural)						
Urban (r)	48 (56%)	37 (44%)	1.00			
Rural	79 (48%)	85 (52%)	1.40 (0.82-2.36)	0.215	1.49 (0.86-2.59)	0.153
Socio-economic status						
Access to motorised transport (r)	119 (54%)	102 (46%)	1.00			
No access to motorised transport	8 (29%)	20 (71%)	2.92 (1.23-6.90)	0.015	3.36 (1.35-8.40)	0.009
Education						
Secondary or above (r)	85 (54%)	71 (46%)	1.00			
None or primary	42 (45%)	51 (55%)	1.45 (0.87-2.44)	0.155	1.02 (0.58-1.80)	0.936
Marital status						
Never married or living together (r)	12 (80%)	3 (20%)	1.00			
Married/living together	112 (48%)	119 (52%)	4.25 (1.17- 15.46)	0.028	3.13 (0.76- 12.91)	0.091
Divorced/separated	3 (100%)	0 (0%)	1.00 (-.)	.	1.00 (-.)	
# living children						
0 (r)	51 (65%)	28 (35%)	1.00			
1 or more	76 (45%)	94 (55%)	2.25 (1.30-3.91)	0.004	2.24 (1.07-4.72)	0.033
# previous abortions						
0 (r)	81 (56%)	63 (44%)	1.00			
1 or more	46 (44%)	59 (56%)	1.65 (0.99-2.74)	0.053	1.68 (0.96-2.94)	0.067
# previous abortions						
0	81 (56%)	63 (44%)	1.00			
1	36 (52%)	33 (48%)	1.18 (0.66-2.10)	0.576	1.26 (0.68-2.33)	0.014
2 or more	10 (28%)	26 (72%)	3.34 (1.50-7.44)	0.003	3.49 (1.45-8.40)	
Previous contraception use						
No (r)	57 (54%)	49 (46%)	1.00			
Yes	70 (49%)	73 (51%)	1.21 (0.73-2.01)	0.452	1.00 (0.57-1.74)	0.997
Contraception decision-making						
Joint decision (r)	70 (51%)	68 (49%)	1.00			
Mainly participant	26 (47%)	29 (53%)	1.15 (0.61-2.15)	0.665	0.89 (0.45-1.76)	0.931
Mainly husband/partner	17 (45%)	21 (55%)	1.27 (0.62-2.62)	0.514	1.06 (0.48-2.35)	
Mobile phone access						
Never shares (r)	65 (52%)	61 (48%)	1.00			
Shares	62 (50%)	61 (50%)	1.05 (0.64-1.72)	0.852	0.99 (0.59-1.68)	0.979
Disclosure of abortion to others						
No (r)	10 (59%)	7 (41%)	1.00			
Yes	52 (49%)	54 (51%)	1.48 (0.53-4.19)	0.457	1.14 (0.36-3.56)	0.825

PAFP intentions						
No (r)	14 (78%)	4 (22%)	1.00			
Undecided	68 (49%)	72 (51%)	3.71 (1.16-11.82)	0.027	2.69 (0.80-9.12)	0.248
Yes	45 (49%)	46 (51%)	3.58 (1.09-11.70)	0.035	2.46 (0.71-8.55)	
Fertility plans						
Have a/another child (r)	82 (53%)	73 (47%)	1.00			
No more/none	34 (50%)	34 (50%)	1.12 (0.63-1.99)	0.690	0.67 (0.34-1.31)	0.388
Undecided	11 (42%)	15 (58%)	1.53 (0.66-3.55)	0.319	1.15 (0.46-2.86)	
Abortion method						
Surgical (r)	80 (54%)	67 (46%)	1.00			
Medical	47 (46%)	55 (54%)	1.40 (0.84-2.32)	0.196	1.85 (1.06-3.22)	0.030
Phone credit						
Always (r)	53 (55%)	44 (45%)	1.00			
Usually	38 (58%)	27 (42%)	0.86 (0.45-1.61)	0.631	0.91 (0.47-1.77)	0.480
Sometimes	36 (41%)	51 (59%)	1.71 (0.95-3.06)	0.073	1.35 (0.73-2.52)	

*Adjusted for age, socio-economic status, residence, education and number of living children

but not in the unadjusted analysis; having one or more compared to no children (unadjusted OR 2.25; 95% CI: 1.30-3.91) which remained statistically significant; having two or more previous abortions as opposed to none (unadjusted OR 3.34; 95% CI: 1.50-7.44) which remained statistically significant; planning to use (unadjusted OR 3.58; 95% CI: 1.09-11.70) or being undecided about PAFP (unadjusted OR 3.71; 95% CI: 1.16-11.82) as opposed to not planning to use PAFP at the time of randomisation but not in the adjusted analysis. Medical compared to surgical abortion became associated with requesting to speak to the counsellor (adjusted OR 1.77; 95% CI: 1.03-3.07) after adjusting for the confounding variables.

6.5 Discussion

Summary of main results

In summary, amongst 249 women that received six interactive voice messages +/- counsellor support for PAFP, around half actively requested to speak to a counsellor (pressed '1') and over 90% spoke to a counsellor at some stage. Women who spoke to the counsellor having requested to (by pressing '1') were more than four times as

likely to be using effective contraception at four months compared to women who didn't request or speak to the counsellor. There was a small, non-statistically significant increase in contraception use amongst women that spoke to the counsellor *without* requesting a call. Increased parity, a history of >2 previous induced abortions, lower socio-economic status, and medical abortion were associated with requesting to speak to a counsellor (pressing '1') after adjusting for age, socio-economic status and residence, education and number of living children.

Strengths & limitations

A strength of this study is the use of prospectively collected quantitative data on participant characteristics and response to the intervention which provides some insight into the active components of the intervention. The main limitation of this study is that it only considers a provider perspective and does not consider the views and experiences of users; this will be assessed in a subsequent paper. The main limitation affecting the logistic regression analysis was the relatively small sample size, particularly in some of the subgroups, resulting in lack of statistical power to detect differences. Hence, whilst odds ratios may appear to vary greatly between subgroups, the confidence intervals are wide, and so these trends should be interpreted with caution. It was not possible to adequately evaluate the effect of the pill or injection reminders as they were sent to a relatively small number of women, without a control group, and part of a complex intervention. A further limitation concerns the generalisability of this study and the findings might not be applicable to other settings.

Interpretation & comparison with existing literature

To our knowledge, this is the first process evaluation of an interactive mobile phone-based intervention for contraception that includes a detailed assessment of provider-

participant communication. Other trials of mobile phone-based interventions to improve contraception use have involved unidirectional text messages, and thus provide limited opportunity for comparison.(142)(143)(144)(229) However, some comparisons can be made with other studies, in particular the process evaluation of the text message component of Lester's intervention for antiretroviral medication adherence.(230)

Response to the intervention

Despite sending the messages at the clients preferred time (e.g. morning or evening), the proportion of participants not responding to voice messages (i.e. pressing '1' or '2') was greater than non-responses to interactive text messages reported in trials in Kenya and the USA.(127)(229) The most likely explanation for this is that our 'real-time' voice message required an immediate response (there was no voice-mail), whereas clients can respond to a text message at their convenience. The proportion of women actively responding to voice messages decreased over time, similar to decrease in responses observed in previous trials of interactive text message or pager interventions.(231)(232)(230)

More women requested to speak to a counsellor at voice message one than at message six and the proportion of women not requesting a call back increased over time, which might be expected as issues were resolved. By message six, 15 (6%) clients had opted out mainly because they reported being too busy or shared their phone with someone else, which is common in Cambodia.(141) Six participants (2%) randomised to the intervention did not receive any messages mainly due to non-functioning phone number. A text message trial in the USA reported similar

intervention discontinuation (42/480; 9%) and number of participants that never received messages (4/480; 0.9%).(142)

Previous studies have reported greater than 40% discontinuation of short-acting methods by 12 months.(233) In our study, 17% of women that received an injectable reminder message and 32% of women that received a pill reminder message had discontinued at four-months. It is not possible to determine the added value of these additional messages within the whole intervention, as we did not have a comparison group of women using pill or injectable not receiving reminder messages. However, pooled analysis suggests that text message reminders for medication adherence have at best small effects.(115) Elsewhere, a trial in the USA reported that participants receiving text message reminders had a lower mean number of days between scheduled appointment and actual attendance for contraceptive injection for the first, but not subsequent appointments.(229)

Assessing associations between interaction with the intervention and contraception use provided further insights regarding possible active components of the intervention. Compared to women that never requested a call (pressed '1') or spoke to the counsellor, women who pressed '1' and spoke to the counsellor were over four times more likely to be using effective contraception at four months. In contrast, there was a lesser, non-statistically significant increase in contraception use amongst women that spoke to the counsellor *without* requesting a call. We did not find evidence that contraception or fertility intentions at the time of seeking abortion services were associated with requesting to speak to a counsellor, after adjusting for the confounding variables. The finding that phoning women who requested a call is associated with subsequent use of effective contraception suggests that the

interactive message can identify a subgroup of women in whom counselling will be more effective.

Public health implications

Our finding that women were more likely to request a call back from a counsellor (pressing '1') if they were of lower socio-economic status or increased parity suggests that the intervention is equitable in terms of engaging those most in-need and could have public health benefits at scale. Older women and those with increased parity are at greater than average obstetric risk from subsequent unintended pregnancies.(1)

Poor women are most likely to experience complications related to unsafe abortion from subsequent unintended pregnancies. (204)

Age was associated with pressing '1' in the unadjusted analysis was because older women were poorer, less educated, had more children or previous abortions and more likely to live in rural areas. In contrast to other studies, we didn't find that residence was associated with response to the voice message.(230) However, it is possible that lack of access to motorised transport (proxy for socio-economic status) was a barrier to accessing face-to-face health services.

Women with one or more child might have requested to speak to a counsellor due to increased motivation to prevent another unintended pregnancy. Engagement by women who have had several abortions could reflect problems with contraception in the past or post-abortion health concerns. Women opting for medical abortion might be more likely to request to speak to a counsellor for support regarding managing their symptoms at home.(178) Although it is safe to use a full-range of contraceptive methods apart from intra-uterine device on the day of medical (misoprostol)

treatment,(29) some women might want to postpone decisions about contraception use until the abortion is complete.

Implications for practice/research

First, given that women were more likely to subsequently use contraception if they requested to speak to a counsellor (i.e. pressed '1'), the intervention could be further refined so that counsellors only phone women that request to speak to a counsellor.

As the cost of counselling is likely to be the main limitation to scaling up the intervention, this change would reduce costs but any effect of the intervention amongst women that speak to the counsellor *without* requesting a call would be lost.

Second, in settings where smartphones use is high, the intervention could be adapted whereby the voice message is sent via an instant messaging application and listened to at the woman's convenience, and can be listened to several times. This might increase the response rate to the messages. Use of such applications provides additional opportunities to add other low-literacy content such as stickers/cartoons and future research could evaluate such interventions.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

CS undertook the data analysis and drafted the manuscript. LS, RW and UV collected data and assisted with the descriptive analysis. PE advised on statistical analysis. CS and CF designed the intervention and the trial. RW, LS, UV, PE and CF commented on the manuscript.

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7. Women's views and experiences of the mobile phone-based intervention

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS

SECTION A – Student Details

Student	Chris Smith
Principal Supervisor	Caroline Free
Thesis Title	Increasing contraception use with mobile phone-based interventions

If the Research Paper has previously been published please complete Section B, if not please move to Section C

Section B – Paper already published

Where was the work published?	N/A		
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Reproductive Health Journal
Please list the paper's authors in the intended authorship order:	Chris Smith ¹ (corresponding author), Sokhey Ly ² , Vannak Uk ² , Ruby Warnock ³ , Caroline Free ¹ ¹ Department of Population Health, London School of Hygiene and Tropical Medicine, Keppel Street, London, WC1E 7HT, UK ² Marie Stopes International, Phnom Penh, Cambodia ³ Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, USA
Stage of publication	Submitted on 10 th September 2016 (editor assigned)

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the first author on this paper. I was responsible for designing the interview topic guides, conducting initial interviews, training research assistants, analysing and coding the data, and drafting the manuscript. My co-authors supported this work in an advisory capacity, assisting with additional coding and helped to edit the writing.
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Student Signature:  **Date: 21/10/2016**

Supervisor Signature:  **Date: 21/10/2016**

Chapter transition notes

The previous chapter (Chapter 6) gained insights into the mechanism of action of the intervention using data collected during the intervention. This chapter (Chapter 7) is a qualitative interview study to assess women's views and experiences of receiving the MOTIF intervention, gain insights into the mechanism of action of the intervention and seek recommendations for improvements.

Women's views and experiences of the mobile phone-based intervention

7.1 Abstract

Background

The MOBILE Technology for Improved Family Planning (MOTIF) trial assessed a mobile phone-based intervention comprising voice messages and counsellor support to increase post-abortion contraception at four Marie Stopes International clinics in Cambodia. The aim of this process evaluation was to assess women's views and experiences of receiving the MOTIF intervention, gain insights into the mechanism of action of the intervention and seek recommendations for improvements.

Methods

We conducted a qualitative study comprising 15 semi-structured interviews with women who had received the intervention and undertook a simple thematic analysis.

Results

We identified themes relating to communication via mobile phone, supporting contraception use, broader post-abortion care, interaction with family and friends and suggestions for improvement. The majority of women were positive about the mobile phone-based intervention to support contraception use and reported it to be a convenient way to ask questions or get advice without going to a health centre, although a few women found the voice messages intrusive.

The intervention supported contraception use by provision of information, encouragement, reminders to return to clinic, reassurance and advice for problems and had a positive effect on contraceptive uptake and continuation. Women reported a sense of being cared for and received support for additional physical and emotional

issues. Most women thought that the duration of the intervention and frequency of messages were acceptable.

Conclusions

The majority of women were positive about the mobile phone-based intervention which provided support for contraception use as well as additional physical and emotional issues. The study provides some insights into how the intervention might have worked and considers how the intervention could be improved.

7.2 Introduction

In recent years several randomised controlled trials have assessed interventions delivered by mobile phone ('mHealth') to improve contraception use.(227)

Interventions have sought to improve adherence to specific methods of contraception such as oral contraceptive or injectable,(142)(143)(229) or improve use of a range of contraceptive methods.(203)(144)(190) To date, the trial evidence for mobile phone-based interventions to increase contraception use is mixed. A mixture of uni-directional and interactive daily educational text messages improved oral contraceptive adherence at six months in the USA.(142) In our MOBILE Technology for Improved Family Planning (MOTIF) trial, a series of voice messages with additional counsellor support improved use of effective post-abortion contraceptive in Cambodia at four but not 12 months.(203) Automated text message reminders did not improve oral contraceptive or injectable adherence in two small trials in the USA.(143)(229) Text messages and role model stories were reported to be associated with increased knowledge but not behaviour change in Kenya.(190) Thus, whilst interventions delivered by mobile phone to improve contraception use show promise, greater

understanding of what works, for whom and under what circumstances is required.

Process evaluation alongside randomised controlled trials can enhance understanding of why a certain intervention works or does not work.(228)(201)

The study reports women's views and experiences of receiving voice messages and counsellor support for post-abortion contraception in the MOTIF trial. The MOTIF trial protocol, results and description of the intervention development are reported elsewhere.(203)(167)(212) In brief, the intervention comprised six automated interactive voice messages over the three-month post-abortion period. Women could press '1' to request to speak to a counsellor, press '2' if they did not require a call back, or press '3' to opt-out of receiving further messages. Phone counselling aimed to increase contraception use by providing information about a range of methods and advice for side-effects. If the woman requested, the counsellor could also discuss contraception with the husband or partner.¹⁴ Clients that chose to receive the oral contraceptive or injectable could opt to receive additional reminder messages appropriate to their method.

Amongst 249 women that received the intervention, around half actively requested to speak to a counsellor (pressed '1') and over 90% spoke to a counsellor at some stage.

Women who spoke to the counsellor having requested to (by pressing '1') were more likely to be using effective contraception at four months compared to women who didn't request or speak to the counsellor (Odds Ratio 4.39; 95% CI: 1.15-16.71).

Increased parity, a history of >2 previous induced abortions, lower socio-economic status, and medical abortion were associated with requesting to speak to a counsellor.(234) This study aims to explore women's views and experiences of

¹⁴ The counselling guide is shown in Appendix 6

receiving the MOTIF intervention, gain further insights into the mechanism of action of the intervention and seek recommendations for improvements.

7.3 Methods

This qualitative study involved 15 semi-structured interviews with women within a few weeks of receiving the intervention. Participants for interview were selected purposively by the counsellor (author LS) delivering the intervention to include women from urban and rural areas and those who did or did not appear to respond to the intervention; both users and non-users of contraception. The counsellor telephoned participants to ask if they were willing to participate in the interview study.

The topic guide was developed to explore women's experience of the intervention, aiming to identify active components of the intervention, and seek recommendations for improvements (Figure 52).

Figure 52: Interview topic guide

1. MOTIF mobile phone-based service

You recently used the new Marie Stopes mobile phone post-abortion service. Could you please tell me about your experience of the service?

a. Voice Messages (outgoing)

I would like to hear your experience regarding the voice messages.

- Tell me what it was like when you received the VMs?
- What did you think about the VMs? / How did it make you feel?
- Can you remember what were you told about the VMs when you signed up?

POSSIBLE PROMPTS

- v. How many voice messages did you listen to?
- vi. Do you recall what the voice messages said?
- vii. What was your understanding of the VMs?
- viii. What were you doing at the time you received the VMs?
- ix. Any comments about the sound quality / voice of the message?
- x. What did you expect to happen if you pressed '1', '2' or '3'?
- xi. Did you respond to the VM?
 - 1. If so, what number did you press, and why?
- viii. Did anyone else listen to the VM instead of you?
 - 1. Any consequences of this?

b. Pill/injection reminders (if relevant)

- i. Did you receive any pill or injection reminder VMs?
 - 1. If so, what was your experience of this?

c. IVR system and leaving messages (incoming)

i. Did you ever call into the service?

1. If so, what was your experience of this?

d. Counselling

- Did you receive any direct phone calls from the counsellor?
If yes,
- What was it like when you spoke to the counsellor?
- What did you think about speaking to the counsellor? / How did it make you feel?

POSSIBLE PROMPTS

- i. What kind of information were you given from the counsellor?
- ii. What support do you receive about post-abortion care? (E.g. medical, emotional)
- iii. What information were you given about contraception?
- iv. What did you think about any advice you were offered about contraception? Any conflict with clinic service provider advice?
- v. Any counsellor contact with husband/partner, any links with model clients
- vi. Where do you think the counsellor is based? Do you think she is old or young? Would like to see her picture before participating in the service?

2. Support/change in behaviour/unintended consequences from intervention

- In general, (thinking about VMs and counselling), did anything happen to you as a consequence of receiving the service (positive or negative)? OR did you do anything different?

- How would this compare to if you hadn't received the service?

POSSIBLE PROMPTS

- i. Any support with SE's/ to continue using method?
- ii. Any support starting or switching to a new method
- iii. Clinic attendances for check up's/post-abortion follow up appointment avoided? Any time/money saved?
- iv. Use other services in addition to MSI? Why?
- v. Any suggestions for the service?

Would anything else have worked better for you? Would you recommend it to a friend seeking abortion services?

POSSIBLE PROMPTS

- Length of service, voice messages versus direct calls etc.
- How could we make it more likely for you to listen and respond to VM?
- Would you be prepared to pay an additional fee for the service? If so, how much?

3. Views on trial

- What was your experience of participating in the trial?

POSSIBLE PROMPTS:

- a. Any comments on the recruitment process (information for participants, consent)?
- b. Any comments on phone follow up?
- c. Any comments on reimbursement to cover time/costs for interviews?
- d. Any suggestions for improvement?

Can I finally ask you for any final comments that have not been covered in this interview?

Questions were included on duration and frequency of messages, content of the intervention and any subsequent behaviour change. Participants were also asked about their experiences of participating in the study and will be reported elsewhere. Participants that attended for clinic interview were given \$4 USD to compensate for travel expenses.

Interviews were conducted between 30 October and 23 November 2013. Author CS conducted six interviews (four at the clinic, and two at clients houses) with author UV interpreting, author RW conducted three interviews (at the clinic) with UV interpreting, and UV conducted six interviews (four at the clinic, and two by phone). Participants were provided with an information sheet to read, or it was read to them, and provided signed or thumb-printed consent, or recorded verbal consent for the phone interviews. Interviews were recorded and transcribed by Cambodian research assistants (medical students) to English. NVivo 11 software was used to store and code all transcripts.(235)

We undertook a simple thematic analysis.(236) This involved familiarization with the interview transcripts, identification of key themes, coding the data according to appropriate thematic references, comparison of themes across and within cases. CS and CF read the transcripts to identify key themes. CS coded all the transcripts and compared themes across and within cases. CF and UV coded some transcripts. Key themes are supported with quotations which have not been edited apart from obvious typos to avoid unintentionally changing the meaning. Ethical approval was obtained from ethics committees at the London School of Hygiene and Tropical Medicine and Marie Stopes International and the Cambodia Human Research ethics committee.

7.4 Results

The characteristics of the 15 interview participants are shown in Table 32.

Participants' age ranged from 22 to 41. Most women were married and employed, but we also interviewed three students and an entertainment worker. Twelve women were using a contraception method at the time of interview, eight of whom were using

long-acting methods (intrauterine device or implant). We identified themes relating to communication via mobile phone,

Table 32: Characteristics of interview participants

No.	Age	Occupation	Marital status	Residence	Post-abortion contraception use
1	22	Housewife	Married or living together	Urban	Used oral contraceptive post-abortion
2	31	Employed	Married or living together	Urban	Didn't use PAFP then had IUD inserted after repeat abortion
3	30	Self-employed	Married or living together	Urban	Returned to clinic for IUD insertion
4	24	Housewife	Married or living together	Rural	Used oral contraceptive post-abortion but discontinued as husband working away. Sent oral contraceptive reminder message
5	33	Housewife	Married or living together	Urban	Used IUD post-abortion
6	34	Self-employed	Married or living together	Rural	Returned to clinic for implant insertion
7	34	Self-employed	Married or living together	Urban	Returned to clinic for IUD insertion
8	34	Factory worker	Married or living together	Rural	Used oral contraceptive post-abortion but discontinued as husband living away
9	25	Student	Married or living together	Rural	Advised to have abortion for medical reasons and avoid pregnancy for a year; using oral contraceptive. Sent oral contraceptive reminder message
10	25	Factory worker	Married or living together	Rural	Returned to clinic for IUD insertion
11	22	Student	Married or living together	Urban	Using oral contraceptive. Sent oral contraceptive reminder message
12	20	Student	Never married or living together	Urban	Using oral contraceptive
13	38	Self-employed	Married or living together	Urban	Used oral contraceptive post-abortion then had IUD inserted
14	41	Farmer	Married or living together	Rural	Used implant post-abortion
15	25	Entertainment worker	Never married or living together	Rural	Not using contraception as not in relationship

supporting contraception use, broader post-abortion care, interaction with family and friends and suggestions for improvement.

Communication by mobile phone

Most women reported that communication via mobile phone was convenient. Women reported listening to the voice message if it was received at a convenient time and

thought the message was easy to understand. Whilst most women had forgotten the content of the voice message, most recalled the concept of pressing a number on their keypad and reported that it was good to have the option to request to speak to a counsellor or not. Women reported pressing '1' if they had a question or health problem or pressing '2' or ending the call if they were busy, had no problems, or did not want to disturb the counsellors.

"Sending voice message wasn't the disturbance because if we wanted to talk to her, we just talked and if we didn't want to talk, we just pressed number 2 or 3 if we didn't want her to call us, she would stop calling us" (interview 11)

"I think that pressing number 1 or number 2 is better because when I face problem, I just press number 1 or number 2... That's why it is quite important for me" (interview 9)

Several women reported that receiving messages or speaking to the counsellor was a convenient way to obtain support for health issues or remind them about contraception and saved the time and costs of clinic attendance.

"These messages help a lot-especially for those who live far away from here like me. Because of busy, I might forget to use contraception methods, but when I listen to voice messages, I can remember. If do not want to have pregnant, I just listen to it. Voice messages always remind me...Whenever I listen to voice messages, I feel like someone stays next to me and supports me about using contraceptive methods" (interview 9)

"Counselling via phone call gives advantage...because we don't have to come to PET [health worker], spend money to clinic directly, and we discuss with her and if we don't discuss with her and we have to come to PET, we spend money first for travel fee and second for PET fee" (interview 6)

Conversely, a few women reported missing calls if they were away from their phone. Two women reported that messages could be intrusive if received at an inconvenient time e.g. when busy at work.

"The message just tell me to click one or two for answer... at that time I still work but if I'm busy, it's ok but sometimes when I'm very busy and like stress and sometimes it's annoying" (interview 2)

Supporting contraception use

Many women reported receiving information and increasing their knowledge on a range of contraceptive methods. Several women reported that the counsellor would ask if they were using a method, and the phone call provided an opportunity for women to ask questions about contraception.

“She explained even about drug, IUD/implant, injection, oral pill, and IUD, and condom. She explained all. She told me a lot” (interview 5)

“The message ended and a short while, she would call me back... I asked her that, for example, we forgot to take the pill... What should I do if [I] forgot taking till 3 days?” (interview 11)

Some women reported that they decided to adopt a long-acting method of contraception after speaking to the counsellor. A few women described being given information on discounts or where to access services.

“After I got information from counsellors I then went to clinic to insert IUD...I learnt how to insert IUD and taking pills. Inserting of IUD is much more easier. Talking pill has to be on time and take it daily but for IUD we do not have to do like this. We can have sex whenever! Counselling service made me feel confident because I thought that medical science is better than our thought. Some people said that IUD can move around, but when I came to ask counsellor, she said that IUD did not have legs to move around.... I also told people I know to insert IUD as well” (interview 10)

“She explained me to have contraception here, use implant at this clinic, there was discount” (interview 6)

Several women reported that the counsellor provided advice if they were experiencing side-effects from contraception; either advising the women to attend the clinic for examination or providing reassurance which led to the women continuing to use the method.

“She said that the side effects of IUD lasted 3 months, I remember that. And after these 3 months, our body can tolerate with it, it will be alright...and now I am alright” (interview 3)

Three women received a specific pill reminder message at one-month, but only one woman recalled receiving this. However, several women using oral contraceptive reported that the counsellor had emphasized the importance of taking the pill regularly and the risk of consequent pregnancy, resulting in a change in behaviour.

“I was confident because she said that when we took the pill, we had to take regularly. If we didn’t take the pill regularly, it was possible to be pregnant... so I changed my habit according to her” (interview 1)

Broader post-abortion care

An important aspect of the intervention was the sense of care and emotional support provided as well as support for specific problems. Many women reported feeling happy because somebody was taking care of them, or asked about their health or more generally about what they were doing. Several women reported that the counsellor provided encouragement and that they gained confidence and felt less afraid.

“For that voice message that I received, I think that it’s good. It’s good and like makes me feel warm like there’s someone take care about us” (interview 8)

“When I received that voice message, I felt that... she encouraged me and she loved our health so that she wanted to know about our health if we were healthy” (interview 12)

One woman reported receiving support for suicidal feelings.

“Struggle in my life, because sometimes I want to commit suicide, but counsellor not allow me to do this, they encourage me to be strong” (interview 15)

The counsellor provided support for post-abortion health concerns such as abdominal pain, vaginal bleeding or discharge. In some cases the counsellor would provide reassurance or otherwise suggest the women attend the clinic for a check up.

“After I used medicine I asked her my problem “why around my abdominal still painful? Why I cannot do something? Even just walking, I cannot walk”.

Counsellor said that bleeding it just side effect of medicine, but if you has much bleeding you need to go back to clinic. I followed up myself and I found that there was just small bleeding, so I decided not coming to clinic” (interview 9)

A few women reported gaining general information about illnesses and health promotion.

“If I make comparison, I see a lot of changing. Before I seldom to hear information, by the time I have started to use services here, I can consult at anytime and I know more about illness problem that often happen to women and its prevention” (interview 9)

Interaction with family and friends

In most cases women listened to the voice messages on their own. Some women reported that they were able to discuss topics in confidence that they couldn't discuss elsewhere or with others, for example, at a hospital or with family members.

“The reason why I believe her because she encouraged me that she wouldn't tell other about my secret and what she talked with me she kept in secret...I believe that they can help a lot of other women, sister, because woman is shy, and sometimes she can't talk to other... it just sometimes we felt embarrassed. There're some matters that we don't want other to know” (interview 12)

A few women reported that they would hang up, or arrange to speak to the counsellor at a different time if messages were received or the counsellor called in the presence of others.

“Sometimes there was my mother; I didn't want to talk because I was shy and I didn't want her to know. But if I stayed with my family, my couple, there was no problem. But sometimes...he didn't stay with me every time, but we didn't want like questioning words like I was sick like this or like that I didn't want to talk in front of my mother, and my younger siblings. But she called me when I was alone or with my family, I would talk and there was no problem” (interview 8)

If few women reported that family members or friends might ask questions after listening to a voice message in their presence, but husbands' were generally supportive.

“No one listens to my voice messages because my phone stays with me all the time. Even my husband, he also does not hack and listen alone. When new message coming, my husband told me... Moreover my husband always asks me questions when I finished listen to messages because he concerns much about my health condition” (interview 9)

In other cases, women reported deliberately sharing intervention content. One woman reported using the speakerphone so that others could listen to the message. There were a few instances where women reported having subsequent conversations with friends or family members to recommend Marie Stopes services or contraception methods.

“I never let anyone listen to it but I brought my younger sister who wanted to use IUD like me. I always told her that I felt well” (interview 3)

There were a few instances where someone else listened to the message or spoke to the counsellor because the phone had been shared with another family member but there were no reported instances of harm as a consequence.

Suggestions for improvement

All of those interviewed thought that the service should be offered to women in the future. One participant suggested focusing on less educated women.

“I do not have any request because it is good enough already. I rarely to see services like this in others organization” (interview 9)

Most women were positive about voice messages, although a few women expressed a preference for direct phone calls or text message. Although most women couldn't remember how frequently they received messages, most reported that a frequency of two times a month was enough.

“I want direct phone call... I am not interested in voice message at all because it takes long time, but if you call me, I once pick up the phone call” (interview 1)

“Text message. Sometimes when I go bathroom when comeback, I can see message rather than missed call.” (interview 15)

Most women thought that the intervention duration of three-months was sufficient and that the messages were no longer required e.g. *“not really necessary for me because I do not have any problem now” (interview 14)*. However, a few women reported that they would have liked the voice messages to continue beyond three months in case they experienced problems in the future.

“There was a message said that this message was the last message. To me, when the message said that it was the last message, I felt regret and I didn’t want” (interview 3)

“Sometimes I don’t know in the future I will meet what problem, sister, so I am difficult to call her. When she sends voice message to me, she has my number and that number is easy for me to call to ask her too” (interview 12)

Most women reported that they would be happy to pay a small fee (e.g. \$1-2USD) for such a service, but a few thought it should remain free of charge. A few women suggested that the messages support other health topics.

“We go to small pharmacies, we have to spend the money too; therefore, I don’t mind about paying this amount. This is for our health too” (interview 3)

“I am interested in general health short voice messages if we send you weekly? For example, messages tell you how to prevent from diseases, how prevent from pregnancy, STI and so on...I want these services still providing for long period” (interview 14)

7.5 Discussion

Summary of main results

The majority of women were positive about the mobile phone-based intervention to support contraception use and reported it to be convenient in a number of ways.

Most women liked being able to respond to the voice message to request to speak to a counsellor or not. However a few women found the voice messages intrusive. Phone counselling was a convenient way to ask questions or get advice without going to a health centre. Women reported that the intervention, in particular phone counselling,

supported contraception use by provision of information, encouragement, reminders to return to clinic, reassurance and advice for problems and had a positive effect on contraceptive uptake and continuation. Women reported a sense of being cared for and received support for additional physical and emotional issues. Counselling allowed women to discuss issues with the counsellor in confidence, although in some cases the intervention content was shared with others, either deliberately or unintentionally. Most women thought that the duration of the intervention and frequency of messages were acceptable.

Strengths & limitations

This study provides insights to the intervention gained by in-depth interviews with women. A strength of our methodology is that most of the interviews were conducted by female researchers, which is considered more appropriate for reproductive health research in order to minimise 'social distance' between researchers and subjects.(237) Our study also has some limitations. It is possible that women would have been more likely to agree to be interviewed if they had had a positive experience of the intervention. We did not document if any women refused to participate. Most of the women interviewed were using a contraceptive method and hence we were unable to assess differences in accounts between contraception users and nonusers. As in the trial, most of the women interviewed were married, and single women and entertainment workers were under-represented.(203) The interviews may have been prone to social desirability bias, particularly as some were conducted by western researchers, although it is encouraging that a range of views were expressed. Although small numbers of women were interviewed, few new ideas resulted from the later interviews, and a degree of 'saturation' was reached.

Another potential limitation is that it wasn't always clear if the woman was referring to voice messages or counselling when analysing the interviews. Hence it was not always possible to attribute women's reports to the automated or counsellor-delivered components of the intervention. As a consequence of these potential biases, it is not possible to conclude that all relevant themes were identified.

Interpretation & comparison with existing literature

To our knowledge, this is the first in-depth interview study reporting participants' perceptions of a mobile phone-based intervention to support contraception use alongside a randomised controlled trial, although participants were asked questions regarding their satisfaction in two RCTs of oral contraceptive adherence interventions in the USA.⁽¹⁴²⁾⁽¹⁴³⁾ Our finding that participants were positive about the intervention is consistent with previous studies assessing participants experience of mobile phone-based interventions in other areas (e.g. HIV medication adherence, maternal and child health, sexual health, smoking cessation).⁽¹⁴²⁾⁽¹⁴³⁾⁽²³⁰⁾⁽²³⁸⁾⁽²³⁹⁾⁽²⁴⁰⁾.

Communication via mobile phone was a convenient way to discuss contraception or health issues, saving money and time in comparison to going to a health centre, as previously reported.⁽²³⁰⁾ Our previous analysis found that the proportion of women that requested to speak to a counsellor (pressing '1') decreased from message one to six,⁽²³⁴⁾ which is consistent with reports from the interviews that health issues often resolved over time.

Our finding that messages could be inconvenient and intrusive for some women highlights the limitation of real-time voice messages as a delivery mechanism,

contrasting with other studies of interventions delivered by mobile phone where participants could check messages at their convenience.(239)(134)

It is unclear if the voice messages improved contraceptive use. Participants in other trials reported that daily educational text messages helped them remember to take oral contraceptive or HIV medication.(142)(143)(230) However, reviews of trials of text messages for medication adherence show limited evidence.(227)(115) In our intervention, the reminder to use contraception appeared to be related to providing general motivation rather than a daily prompt.

Interview findings suggest that the intervention included components identified as best practices for contraception counselling including developing close personal relationships, building trust, and adequate counselling regarding side-effects,(241) which may not have been possible with a fully automated intervention. It is not clear to what degree provision of information about discounted services influenced uptake as clients still had to pay a user fee and incur associated travel and opportunity costs. All women would have received contraception counselling at the time of seeking abortion services, as per current recommendations.(29) Findings from this study indicate some benefits to providing on-going support for women to reconsider their contraceptive options and provide support for side-effects as they arise.

The intervention provided additional benefits that were broader than the trial definition of success (i.e. contraception use). Our findings resonate with other qualitative studies of mHealth interventions that reported a feeling that someone cares.(230)(240) The action of sending messages ('push') to participants may contribute to this feeling, as previously reported.(242)(239)

Our finding that women received support for management of physical and emotional health issues is consistent with studies elsewhere; post-abortion mobile phone follow up was demonstrated to reduce women's anxiety and stress in South Africa,(178) and be acceptable and preferable to a clinic visit in the UK.(177)

Although there were no reports of any adverse events as a result of others listening to messages, our interview participants were mostly married and more likely to have disclosed having had an abortion to others. Women concerned about others listening to messages may have elected not to receive the intervention. Phone sharing is common in Cambodia and possible unintended consequences should be considered when developing future intervention content.(141)

Other evaluations of text message interventions for contraception and sexual health have found that participants would re-read messages which might lead to conversations with family or friends.(239)(146) Although this was not possible with our voice messages, some women reported recommending long-acting contraception or Marie Stopes services to other people. This additional contraception use was not captured with the trial follow up but could be evaluated in further studies.

Mechanism of action

This study provides some insight into the mechanism by which the intervention resulted in behaviour change. The voice messages appeared to act as a conduit for additional support rather than directly influencing behaviour change, but may have promoted engagement in the intervention, as previously reported.(243)

The majority of support for contraception uptake and continuation and other post-abortion issues appeared to be provided by the counsellor calls rather than the voice message. The counselling addressed *intrapersonal* determinants of contraceptive use,

in particular health concerns, as well as *capability, motivation* and *opportunity* to use contraception, as per our conceptual framework.(50)(3)(100) The relatively intensive intervention whereby the counsellor could develop a relationship with the woman and deliver personalised support over a short duration likely influenced uptake of long-acting methods such as intrauterine device and implant, but was less effective for continued adherence to short-acting methods.(203)

The intervention included five behaviour change techniques; two could be attributed to the voice messages (*provide instruction*, and *prompt practice*) and three to the counselling (*provide information about behaviour-health link*, *provide information on consequences*, *prompt barrier identification*).(227)(104) Findings from this study suggest that another component of the counselling was to *provide general encouragement*. In general the wider literature suggests that multi-faceted, more complex interventions are more likely to be effective.(244)(134)(115)

Improving the intervention

Most women thought the service should be offered to women in the future with few suggestions for improvement. There was no evidence that the intervention effect varied by level of education.(234)

Some women expressed a preference for direct phone calls or text message but this appeared to be due to timing of the message and concern about missing the call. Most women thought that the frequency of messages and duration of the intervention were acceptable, although as with previous trials of oral contraceptive reminders, some would have liked the intervention to continue;(142)(143) perhaps more as a 'safety net' to support general health.

Our intervention increased effective contraception use at four-months, soon after the intervention had ended, but an effect was not demonstrated at 12 months partly due to the trial not being powered for the outcome at 12 months and increased attrition at 12 months. A previous trial of text message reminders for OC adherence found the intervention effect was greater whilst the intervention was on-going rather than after the intervention ended.(142) This raises the question of whether a longer intervention would have resulted in a more sustained effect. However, evidence that interventions encouraging medication adherence are more effective for short-term rather than long-term treatments suggests only modest improvements might be expected.(134)

Implications for practice/research

Findings from this analysis have some implications for practice and future research. Our findings suggest there may be benefits from providing this intervention (such as increased use of long-acting methods) but the long-term effects require further evaluation. Future interventions for post-abortion contraception could consider including messages to support comprehensive post-abortion care more broadly and should anticipate that women may have a range of issues and be prepared to manage these safely. The intervention could be adapted for use on smart phones and could utilise password protected voice or text messages that are retained on the participants phone. This might improve the response to messages and facilitate sharing of intervention content with others. We recommend that mobile phone-based interventions for on-going support for PAFP should be integrated with counselling at the time of seeking services. Operational research could examine clients' actual willingness to pay for such interventions, and the effect of varying the duration of the

intervention. Further adequately powered trials of mobile phone-based interventions to support contraception use are needed.

Conclusions

The majority of women were positive about the mobile phone-based intervention which provided support for contraception use as well as additional physical and emotional issues. The study provides some insights into the possible mechanism of action and considers how the intervention could be improved.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

CS undertook the data analysis LS identified potential interview participants. CS, RW and UV conducted the interviews. CS undertook the analysis of the interviews and drafted the manuscript. UV and CF reviewed some of the interview transcripts. CS and CF designed the intervention and the trial. RW, LS, UV, and CF commented on the manuscript.

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8. Discussion and conclusions

Findings from each research component of this thesis have been discussed in each of the papers in Chapters 2-7. The discussion section of each of the papers presenting research findings are presented according to the author guidelines for the particular journal. This final chapter summarises the principal findings, presents overall strengths and limitations of the thesis, synthesises the overall study findings in related to the original conceptual framework and existing literature, presents an updated conceptual framework, and discusses implications for future research and practice.

8.1 Principal findings

Findings from this thesis suggest that interventions delivered by mobile phone can increase contraception use, but the evidence to date is mixed. The first objective of the thesis was to conduct a systematic review. Five trials were identified, two of which increased self-reported contraception use (Chapter 2); one of which was four-month data from the MOTIF trial. However, the three trials that did not report an effect were small and potentially underpowered. A meta-analysis was not possible due to differing interventions and outcome measures, with insufficient evidence to recommend particular intervention content or mode of communication. The trials reporting increased contraceptive use were more complex; one involving a range of educational text messages and the MOBILE Technology for Improved Family Planning (MOTIF) trial comprising interactive voice messages with counsellor support. However, the effect of the interventions appeared to diminish over time. Data on cost-effectiveness was lacking.

Subsequent to conducting the systematic review, in addition to the 12-month MOTIF trial follow up, only one of the previously identified ongoing trials has reported results; the m4RH evaluation (see Section 2.8). However this trial had several limitations and it is unlikely that this would have changed the conclusion of the systematic review.

The second objective of the thesis was to develop an intervention delivered by mobile phone to support post-abortion contraceptive use in Cambodia. In developing the conceptual framework and intervention it was hypothesised that a multi-faceted intervention delivered by mobile phone would remind clients about contraceptive methods, identify problems with side-effects early, provide support, and boost motivation to use PAFP, while reducing discontinuation and unsafe method switching (Chapter 3).

The third objective of the thesis was to evaluate the intervention with a randomised controlled trial. The study protocol and update describe the study design and analysis plans (Chapter 4). The intervention was associated with increased self-reported use of effective contraception at four months post-abortion (64% vs. 46%; RR 1.39, 95% CI 1.17-1.66; $p < 0.001$), but not at 12 months (50% vs. 43%; RR 1.16, 95% CI 0.92-1.47; $p = 0.208$) (Chapter 5). The intervention was associated with increased self-reported use of long-acting contraception (IUD, implant or permanent method) at four and 12 months. The intervention was associated with increased effective contraceptive use for >80% of the follow up period at four and 12 months. There was some evidence of reduced discontinuation of effective contraception at four, but not 12 months. The intervention had no significant effect on the repeat pregnancy or abortion rate. There were no reports of adverse effects.

The fourth object of the thesis was to conduct a mixed methods process evaluation.

Around half of the women that received the intervention actively requested to speak to a counsellor (pressed '1') and over 90% spoke to a counsellor at some stage (Chapter 6). Women who spoke to the counsellor having requested to (by pressing '1') were more than four times as likely to be using effective contraception at four months compared to women who didn't request or speak to the counsellor. There was a small, non-statistically significant increase in contraception use amongst women that spoke to the counsellor *without* requesting a call. Increased parity, a history of >2 previous induced abortions, lower socio-economic status, and medical abortion were associated with requesting to speak to a counsellor (pressing '1') after adjusting for age, socio-economic status and residence.

The majority of women were positive about the intervention and reported it to be a convenient way to ask questions or get advice without going to a health centre (Chapter 7). Women reported that the intervention, in particular phone counselling, supported contraception use by provision of information, encouragement, reminders to return to clinic, reassurance and advice for problems and had a positive effect on contraceptive uptake and continuation as well as supporting post-abortion care more broadly.

8.2 Strengths and limitations

The strengths and limitations of each of the research components are discussed in each chapter. In this section I will discuss and expand on some of the main strengths and weaknesses.

Overall strengths

The thesis has some overall strengths. First, to my knowledge, this was the first trial of an intervention delivered by mobile phone to support PAFP. The systematic reviews in

Chapters 1 and 2 identified few studies of interventions delivered by mobile phone for contraception, with the majority in high-income settings. Therefore a strength was that this study was conducted in a low-income setting where consequences of unmet need for contraception and unsafe abortion are greater, and hence interventions have significant potential public health benefits. This study is also unusual in that it used voice messages rather than text messages, as is the case in most other trials. An additional strength concerns the completeness and transparency of reporting. The intervention development (including conceptual framework) was fully described. The trial protocol was published setting out the methods and changes to the analysis plan were published.

Strengths of the Cochrane systematic review

The systematic review in Chapter 2 was rigorous and involved an extensive search strategy and all the elements that are required for a Cochrane review including data extraction on outcomes, double assessment of bias and assessment of quality. In addition, the interventions were coded according to their behaviour change techniques. As a result of conducting rigorous systematic review searches we were confident that we were not repeating a trial already undertaken.

Strengths of the intervention development

As discussed in Chapter 3, a strength of the intervention was that it was developed with significant input from services providers and service users in Cambodia, and it also considered relevant literature on theory of behaviour and behaviour change. As such it was possible to gain an understanding of what types of interventions had been successful, and avoid repeating mistakes of unsuccessful projects. Thus, the intervention was delivered to both users and non-users of contraception on a range of

contraceptive methods in contrast to previous mHealth contraception interventions focusing on one particular method, often the oral contraceptive. Therefore as well as providing support for side-effects to reduce discontinuation, the intervention supported safe-method switching. The finding that text messages were unlikely to be successful was a key finding from the formative research which led to the development of a voice-based intervention.

Strengths of the trial

The trial was assessed for quality of evidence and risk of bias in Chapter 2, and further discussed in Chapter 5. Overall, the quality of evidence for the MOTIF trial using the GRADE approach was considered high and not downgraded across any domains (Table 8). Additional strengths were that the statistical analysis plan was sealed prior to commencing data analysis and all analyses were carried out on an intention-to-treat basis.

In terms of bias, the trial was at low risk of selection bias with adequate procedures to ensure random sequence generation and allocation concealment; allocation was concealed to clinicians and RAs working on the trial. The trial was a low risk of detection bias as researchers undertaking data collection and analysis were masked to treatment allocation. The possibility of social desirability or recall bias is discussed in the limitations section. The follow up rate at four months was high and there was no evidence of any difference in loss to follow-up between the treatment groups (Table 18) and therefore the trial was a low risk of attrition bias. Few trials of post-abortion family planning have a longer observation period than this study.(93) However, we only achieved 66% follow up at 12 months; this will be discussed in the limitations section.

Strengths of the process evaluation

A strength of the process evaluation study was that it included quantitative and qualitative components. As discussed in Chapter 6, the use of prospectively collected quantitative data on participant characteristics and response to the intervention provided some insight into the active components of the intervention. As discussed in Chapter 7, the interview study provided additional insights to the intervention gained by in-depth interviews with women.

Overall limitations

This thesis is subject to several overall limitations. An overall limitation concerns the generalisability of this study. Although the study population appeared to be representative of MSI clients seeking abortion services in Cambodia during 2013 (section 5.6), the findings might not be applicable to other settings.

Limitations of the literature review

The literature review undertaken for my PhD upgrade was conducted by myself and therefore cannot be considered a systematic review. Furthermore, due to time limitations the search strategy only included four electronic databases, and did not search clinical trial registries. However, the Cochrane review did fulfil the criteria for a systematic review, with a wider search strategy and a second review author to screen and extract data.

In both the literature review in Chapter 1 and the systematic review in Chapter 2, studies were excluded in which mobile phones were used for two-way voice communication alone. However, some of the excluded studies were recent and utilised mobile phones for voice calls alone, such as the Kirby study mentioned in the background section of Chapter 4.(174) By only including interventions delivered by

mobile phone that included some degree of automation, such as text message or mobile application, the literature reviews were probably more focussed. However future reviews should consider inclusion of studies using mobile phones more broadly. Furthermore, the literature reviews did not include all of the non-trial mobile phone-based contraception initiatives that have been launched in low-income settings such as Mobile for Reproductive Health (m4RH), Cycle Tel, Mobile Alliance for Maternal Action (MAMA).(146)(149)(147) In addition to systematic reviews of trials of interventions delivered by mobile phone for contraception, a review of non-trial evidence might be useful.

Limitations of the intervention development


As discussed in Chapter 3, a limitation of the formative research is that analysis of the interviews and FGDs was not undertaken by a second coder. Furthermore, I could have reviewed each aspect of the literature more systematically. Time and resource constraints limited the time I could spend on the intervention development.

An additional limitation of the intervention development paper and subsequent papers is that beyond describing the message content, context and software programme used to send messages, there is limited description of the technical features of the intervention that could aid replication of the intervention elsewhere. Subsequent to the publication of the intervention development paper, the World Health Organization mHealth Technical Evidence Review Group (mTERG) published a proposed mHealth Evidence Reporting and Assessment (mERA) checklist to improve reporting of mHealth interventions.(245) To address this limitation, the MOTIF intervention is described according to the 16 items in the mERA checklist in Table 33.

Table 33: Reporting of the MOTIF intervention according to the mERA checklist

Criteria	Item no	Criteria	Notes
Infrastructure (population level)	1	Clearly presents the availability of infrastructure to support technology operations in the study location. This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context. Reporting X% network coverage rate in the country is insufficient if the study is not being conducted at the country level	The intervention was delivered to participants' mobile phones meaning that only intermittent access to electricity/power was required to charge the devices. Electricity was generally reliable at the site of intervention delivery, with a back-up generator available if required. Network coverage rate in the specific areas was not explicitly stated.
Technology platform	2	Describes and provides justification for the technology architecture. This includes a description of software and hardware and details of any modifications made to publicly available software	Based on user feedback (see Item 7) we required voice message software. The only two options we were aware of were FreedomFone (http://www.freedomfone.org/) and Verboice (https://verboice.instedd.org/). Verboice had better functionality for sending interactive messages and InSTEDD had a support office in Phnom Penh. The web-based software was connected to an analogue modem in the InSTEDD office.
Interoperability / Health information systems (HIS) context	3	Describes how mHealth intervention can integrate into existing health information systems. Refers to whether the potential of technical and structural integration into existing HIS or programme has been described irrespective of whether such integration has been achieved by the existing system	The Verboice voice messaging system was not integrated with any existing health information systems, and could be considered a closed system at Marie Stopes International Cambodia. Reporting was as per the trial and process evaluation. Further interoperability could be considered in the future.
Intervention delivery	4	The delivery of the mHealth intervention is clearly described. This should include frequency of mobile communication, mode of delivery of intervention (that is, SMS, face to face, interactive voice response), timing and duration over which delivery occurred	The frequency/duration of messages (six messages; one message every two weeks) and mode of delivery (interactive voice messages with phone call depending on response to message) is described in sections 3.4, 4.3 and 5.3
Intervention content	5	Details of the content of the intervention are described. Source and any modifications of the intervention content is described	The content of the voice message and aim of the counselling is described in sections 3.4, 4.3 and 5.3. See the counselling guide in Appendix 6 for additional details of the phone counselling content
Usability / content testing	6	Describe formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate	The formative research to develop the intervention including participant input in the content of messages and usability testing is described in the intervention development paper (Chapter 3)
User feedback	7	Describes user feedback about the	User feedback through interviews or

		intervention or user satisfaction with the intervention. User feedback could include user opinions about content or user interface, their perceptions about usability, access, connectivity, etc.	focus groups was used as part of formative research to develop the intervention (Chapter 3) as well as to assess women's views and experiences of receiving the intervention (Chapter 7).
Access of individual participants	8	Mentions barriers or facilitators to the adoption of the intervention among study participants. Relates to individual-level structural, economic and social barriers or facilitators to access such as affordability, and other factors that may limit a user's ability to adopt the intervention	Participants needed to have a mobile phone to receive the intervention but affordability was less of issue as there was no cost to receive or respond to messages. Women in whom abortion might be more stigmatised (e.g. single women, students) may be less likely to adopt the intervention due to concerns about privacy and confidentiality.
Cost assessment	9	Presents basic costs assessment of the mHealth intervention from varying perspectives. This criterion broadly refers to the reporting of some cost considerations for the mHealth intervention in lieu of a full economic analysis. If a formal economic evaluation has been undertaken, it should be mentioned with appropriate references. Separate reporting criterion are available to guide economic reporting	For the trial results paper (section 5.5) we estimated the main cost of delivering the intervention (i.e. voice messages, phone calls and counsellor time) to be \$6 per participant. A cost-effectiveness analysis is being undertaken and will be reported elsewhere. Verboice is open-source and free to use, but organisations with limited technical capacity are likely to require additional expertise/support to connect Verboice to a modem to be able to schedule and send messages.
Adoption inputs / programme entry	10	Describes how people are informed about the programme including training, if relevant. Includes description of promotional activities and/or training required to implement the mHealth solution among the user population of interest	During the trial, potential participants were identified by service providers and information about the programme was provided by research assistants. In a non-trial implementation setting, clinic staff such as receptionist or service providers would need to provide information about the programme, but more detailed information could be provided by phone counsellors
Limitations for delivery at scale	11	Clearly presents mHealth solution limitations for delivery at scale	The analogue modem used in the trial could only handle one message at a time. Due to the numbers of participants it was possible to schedule messages one at a time. To deliver the intervention at scale it should be possible to use a digital modem capable of sending multiple messages simultaneously. Additional limitations to scale would be the need to have additional counsellors and provide training to clinic staff to recruit participants to receive the intervention.
Contextual adaptability	12	Describes the adaptation, or not, of the solution to a different language, different population or context. Any	For our study population, voice messages in the Khmer language were required due to limited literacy and

		tailoring or modification of the intervention that resulted from pilot testing/usability assessment is described	inability to text in Khmer language. Participants requested that the terms 'contraception' and 'Marie Stopes' were used. The intervention might require adaptation in terms of mode of delivery and terminology in other settings.
Replicability	13	Detailed intervention to support replicability. Clearly presents the source code/screenshots/ flowcharts of the algorithms or examples of messages to support replicability of the mHealth solution in another setting	<p>The content of the voice message and aim of the counselling is described in sections 3.4, 4.3 and 5.3. The basic flowchart for the interactive voice message is shown here.</p> 
Data security	14	Describes the data security procedures/ confidentiality protocols	The Verboice system was password protected and the password was changed every two weeks. No client information was stored on the Verboice system apart from the phone number required to send messages. A password protected excel form was used to store data from the trial.
Compliance with national guidelines or regulatory statutes	15	Mechanism used to assure that content or other guidance/information provided by the intervention is in alignment with existing national/regulatory guidelines and is described	The counsellors were trained Cambodian midwives and information provided was in line with Cambodia Ministry of Health guidance. The intervention was discussed with the Reproductive Health National Programme Manager in Cambodia and local ethical approval was granted
Fidelity of the intervention	16	Was the intervention delivered as planned? Describe the strategies employed to assess the fidelity of the intervention. This may include assessment of participant engagement, use of backend data to track message delivery and other technological challenges in the delivery of the intervention	There were no major issues and the intervention was broadly delivered as planned. On one occasion the Verboice server was down, but this was rectified quickly (within 24 hours) and there was no significant disruption to message scheduling. The process evaluation revealed that there was often no response to the messages (Section 6.4). This is likely because the voice message was live (i.e. requiring an immediate response) but another possible reason is that due to the analogue modem the voice message started to play immediately after being sent. This meant that we had to create a 30 second countdown to playing the message in case the participant did not pick up the phone immediately.

This additional reporting may be of use to organisations considering implementing similar interventions and use of the mERA checklist should be considered when describing future interventions.

Limitations of the trial

The trial had several limitations that have been discussed in Chapters 2 and 5.

The first limitation pertains to the sample size and study power to assess longer-term trial outcomes. The trial with 500 participants was powered to detect a 13% improvement in the primary outcome, effective contraception use. At four months we achieved 86% follow up and there was an 18% improvement in contraception use (64 vs. 46%) and a statistically significant effect was observed. However, at 12 months follow-up was 66% with just a 7% improvement in use of effective contraception (50% vs. 43%) and hence no statistically significant effect was observed. There was no evidence of differential loss to follow-up and there was no significant change in the principal findings when we estimated the effect of the intervention on the primary outcome at 12 months using multiple imputation (section 5.8). Increased attrition at 12 months was probably due to participants migrating for work and/or changing phone numbers, which is recognised as a challenge for mobile phone-based interventions in Cambodia.⁽¹⁴¹⁾ As discussed in section 5.8, future trials aiming to assess longer-term outcomes or with younger participants or those of lower socio-economic status may require larger sample sizes and use of multiple imputation methods to assess outcomes.

In terms of bias, the trial was at high risk of performance bias as the outcome may have been influenced by lack of blinding. The trial had a high risk of social desirability and recall bias due to self-report measures of contraception use. For the trial, we did

not consider it feasible to measure objective contraception use, for example using biomarkers or with electronic medication monitors, for several reasons as discussed in Chapter 5. Therefore assessment of the primary outcome, use of effective contraception was self-report by phone call. Self-report measures showed fair/good reliability when comparing the four and 12-month data, and the objective measurement validity study did not identify any cases of misclassification. However, the method for verifying self-reported OC use by pill counts was also prone to detection bias. Although self-reported data on contraception use are considered less reliable, and prone to the aforementioned biases, it is the standard approach for contraception research and provided data comparable to previous studies.(189)(188)

An additional limitation is that the method to restrict randomisation to balance prognostic factors across treatment groups was poorly described in trial protocol, statistical analysis plan and results paper. It was incorrectly stated that we stratified participants according to urban or rural clinic status. In fact, minimisation was used. To clarify, stratification involves grouping participants into strata defined by baseline characteristics and performing block randomisation within each stratum whereas with minimisation participants are not grouped into different strata. With minimisation, for each new participant entering a trial, the baseline characteristics of participants in the treatment groups are summarised and the participant is allocated to the group that would provide the best marginal balance in terms of prognostic factors.(246)(247)

As balanced randomisation introduces correlation between treatment groups, violating the statistical assumption that all participants are independent, it has been recommended that variables used in the randomisation process should subsequently be adjusted for in the analysis. However, the extent to which that occurs or is

discussed is variable.(248) Unadjusted analyses after stratification or minimisation can lead to confidence intervals that are too wide, p values that are too large, and a reduction in power resulting in results that are likely to be overly conservative with less chance of a false positive result or type 1 error. This is likely to be issue if the balancing factor is associated with the outcome and whilst unlikely to affect trials that show a large treatment effect, could affect interpretations where there is moderate evidence. It has been argued therefore that adjusting for balancing factors in the analysis is necessary to obtain correct P values and avoid a loss in power i.e. to show a statistically significant result if one exists. Furthermore, rather than undertaking exploratory analyses to determine if the selected balancing factors are associated with the outcome, trial protocols and statistical analysis plans should pre-specify that all balancing factors are adjusted for the in the analysis.(248)

Although not described in the trial protocol or results paper, the reason that we did not undertake simple randomisation was due to concern that this could result in a chance imbalance in participants reporting to live in urban or rural residence, a suspected important prognostic factor that could be associated with the outcome as distance to access services could affect uptake of contraception services. Therefore participants were allocated to the intervention or control group using minimisation by self-reported urban or rural residence. However, there was no discussion in the trial protocol or results regarding whether the minimisation variables analysis should be adjusted for in the analysis. This raises the question of whether an adjusted analysis should have been undertaken to take into account that we used minimisation to balance urban/rural residence across treatment groups. Based on the literature summarised above, strong consideration should have been given to pre-specifying that

urban/rural status should have been adjusted for in the analysis. However, it is unclear that an adjusted analysis would have resulted in a significant change to the principal findings which if anything were likely to be overly conservative, particularly the statistically significant effect observed at four-months. Furthermore, we only minimised for one variable and it has been reported that minimisation balances baseline variables marginally.(249) Careful consideration with regards to balancing prognostic factors across treatment groups and subsequent analysis is required for future trials.

Limitations of the process evaluation

As discussed in Chapter 6, the main limitation affecting the logistic regression analysis was the relatively small sample size, particularly in some of the subgroups, resulting in lack of statistical power to detect differences. Furthermore, it was not possible to adequately evaluate the effect of the pill or injection reminders as they were sent to a relatively small number of women, without a control group.

As discussed in Chapter 7, the process evaluation interviews were subject to social desirability bias. Additionally it is possible that women would have been more likely to agree to be interviewed if they had had a positive experience of the intervention. Most of the women interviewed were using a contraceptive method and, as in the trial, most of the women interviewed were married, and single women and entertainment workers were under-represented.(203) It was not possible to improve reliability of language transcription by getting sections translated by an independent translator due to resource limitations.

Differences between women seeking medical vs. surgical abortion

An additional potential limitation of this thesis is that potential differences between women seeking medical versus surgical abortion were given little consideration during the intervention development. It is possible that there are differences in baseline characteristics and post-abortion family planning intentions in women who opt for a medical abortion compared to a surgical abortion. In the subgroup analysis in Figure 49, there was no evidence of heterogeneity (i.e. that the effect of the intervention varied amongst women having either a medical or surgical abortion). It is safe to use a full range of contraceptive methods apart from the intra-uterine device on the day of medical (misoprostol) treatment and therefore the content of the counselling in terms of contraception advice could have been similar whether women had medical or surgical abortion.

Medical compared to surgical abortion was associated with increased odds of requesting to speak to the counsellor (adjusted OR 1.77; 95% CI: 1.03-3.07) after adjusting for the confounding variables which may have been related to seeking support regarding managing their symptoms at home, i.e. broader post-abortion care. An additional analysis of the trial dataset assessing differences in contraception use and subsequent pregnancies and abortions comparing women who had medical compared to surgical abortion could be useful to aid future intervention design.

Lack of cost data

A final important overall limitation of this thesis is that it does not include a cost-effectiveness analysis. As mentioned in Chapter 5, the main cost of delivering the intervention (i.e. for voice messages, phone calls and the counsellors' time) was estimated to be 6 United States dollars per client. This was based on, as yet

unpublished, data collected during the intervention on voice message, phone call and human resource costs.

A cost-effectiveness analysis of the MOTIF intervention is currently being undertaken and will be published separately. It will assess the cost-effectiveness of mobile phone-based support in addition to standard care versus standard care alone by calculating the incremental cost effectiveness ratio (ICER) under different scenarios, where C_m is the mean cost of the MOTIF intervention alongside standard care, C_s is the mean cost of standard care, E_m is the mean effect of MOTIF being available alongside standard care and E_s is the mean effect of standard care. The main measure of effect will be Couple Year of Protection (CYP), a commonly used measure of family planning performance that equates to one year of contraceptive protection per couple. CYP is calculated by multiplying the number of clients attending for services by corresponding conversion factors to estimate the total amount of contraceptive protection provided and enables comparison with other analyses.⁽²⁵⁰⁾⁽²⁵¹⁾ A sensitivity analysis will consider different user and provider perspectives and uncertainties with respect to effectiveness. More information on the cost-effectiveness of the intervention is likely to be useful for service providers and funders when considering implementation of interventions delivered by mobile phone.

As discussed in Chapter 2, none of the studies identified in the systematic review included data on intervention costs, although we may have identified articles if we had explicitly searched for cost-effectiveness analyses. It has been suggested that one of the reasons that many mHealth interventions fail to continue beyond the pilot stage is the limited data on cost-effectiveness of programmes and mechanisms for financial sustainability.⁽¹²¹⁾⁽¹²²⁾⁽¹³⁵⁾ For implementing organisations, evidence of

effectiveness in terms of health outcomes alone is unlikely to be enough when deciding what activities and interventions to prioritise. The m4RH study mentioned in section 2.8 exploring sustainable cost models for mHealth at scale is a valuable contribution to the literature,(135) but further evidence on the cost-effectiveness of interventions delivered by mobile phone is required.

8.3 Meaning of the study: possible mechanisms in relation to other studies

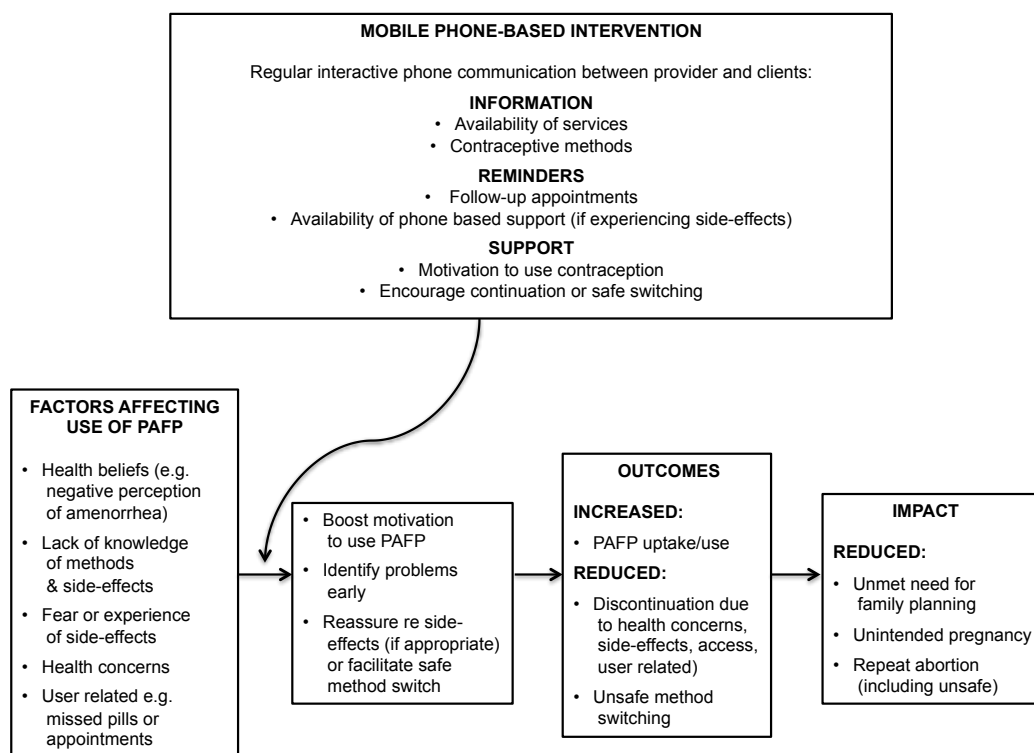
I will now discuss the findings of the trial and process evaluation with reference to the study hypothesis, conceptual framework (displayed again in Figure 53), and existing literature. I will first consider impact (the contribution of the intervention towards sustained significant change), then outcomes (medium/long-term results) and then the mechanism of action of the intervention.

Impact of the intervention

The conceptual framework hypothesised that the intervention would reduce unmet need for family planning and reduce repeat unintended pregnancy and abortion.

Findings from the trial suggested reduced unmet need for family planning as evidenced by increased effective contraception use at four-months, increased self-reported use of long-acting contraception (in particular IUD and implant) at four and 12 months, and increased effective contraceptive use for >80% of the period at four and 12 months. However, the statistically significant increase in follow up use of effective contraception was not demonstrated at 12 months. Reports from the process evaluation interviews supported the trial findings that the intervention reduced unmet need for contraception by providing information, encouragement, and reassurance and support for side effects.

Figure 53: Conceptual framework for intervention



The intervention had no significant effect on the repeat pregnancy or abortion rate but the trial was not powered for these outcomes. A larger trial might have detected a difference in the repeat pregnancy rate observed in the trial (13% intervention vs. 18% control). As previously discussed, previous studies have shown that post-abortion use of long-acting contraception is associated with reduced unintended pregnancies.(36)(37)(38)

Outcomes of the intervention

The conceptual framework hypothesised that the outcomes of the intervention, contributing to impact, would be increased PAFP uptake/use and reduced discontinuation and unsafe method switching. Findings from the additional trial analysis in section 5.6 provided further insights on contraception use with regards to

differences in uptake, discontinuation and switching over the post-abortion period between the intervention and control groups.

This analysis suggested the intervention effect was primarily due to increased initiation of long-acting methods (IUD and implant) whilst receiving the intervention over the three-month post-abortion period. The increase in long-acting method use was sustained at 12 months as women were more likely to continue using these methods, which is consistent with existing literature that short-acting methods have higher discontinuation rates.⁽¹⁶⁾ Increased continuation of long-acting methods in this context might reflect increased satisfaction with the method, but also that the oral contraceptive and injectable can be easily discontinued by the user, whereas intra-uterine device and implant require removal at a clinic.

The relatively intensive intervention whereby the counsellor could develop a relationship with the woman and deliver personalised support over a short duration likely influenced uptake of long-acting methods but was less effective for continued adherence to short-acting methods.⁽²⁰³⁾ Other studies of interventions of enhanced counselling for women at the time of seeking abortion services in the UK and New Zealand have also shown that increases in long-acting reversible contraception use can be achieved.⁽⁹⁵⁾⁽²⁵²⁾

In contrast to the evidence of increased uptake of contraception, there was limited evidence that the intervention reduced discontinuation or supported safe method-switching. There was some evidence of reduced discontinuation of effective methods during the first four-months (HR 0.45 (0.20-1.01)), due to trends towards reduced method specific discontinuation and safe-method switching in the intervention group. However, at 12 months, discontinuation and patterns of safe-switching in the

intervention and control groups were more similar. There was a trend towards increased oral contraceptive discontinuation in the intervention group which was difficult to explain. The trend towards increased injectable discontinuation in the control group at four and 12 months could reflect concerns about amenorrhoea, which appears to be a particular issue in Cambodia, although there was no evidence of this from the process evaluation interviews.(78)(6) The high discontinuation rates observed appear to support the recommendation by Ali and Cleland that *“the prudent course of action is for family planning service providers to anticipate that substantial minorities of couples will cease use of a chosen method, usually within a few months of adopting it, and will need to switch promptly to an alternative if an unintended pregnancy is to be averted”*.(16)

Achieving sustained behaviour change

The finding that the intervention effect was greatest during and shortly after the intervention completed, and less so when assessed several months later, highlights the challenge of achieving sustained behaviour change. As Ogden noted, *“even though many people show initial changes in their health-related behaviours, rates of sustained behaviour change are poor”*.(50) This has been demonstrated in other healthcare fields such as with interventions for weight loss and smoking cessation where relapses have been observed over the longer term.(50)(253) A Cochrane review found that interventions encouraging medication adherence are more effective for short-term rather than long-term treatments.(134) This short-lived behaviour change was also observed in the Castano trial identified in the systematic review (Chapter 2) where oral contraceptive continuation was highest in the intervention group if follow up took

place while the intervention was ongoing, compared to after the intervention ended.(142)

A study in 2008 sought to explore the mechanisms behind sustained behaviour change by conducting qualitative interviews with 34 ‘success stories’ who had lost weight or stopped smoking and maintained the change for at least three years.(254) The results showed that in the majority of cases sustained behaviour change was triggered by a significant life crisis such as a health scare, a salient milestone (such as turning 30), or a relationship break up. The study authors proposed that mechanisms underlying longer term changes may be different to those identified as central to changes in the shorter term and recommended further research to explore whether a crisis is necessary for sustained behaviour change.(254)

In the context of post-abortion contraception, it is possible that having an abortion represents a life crisis, an ‘*epiphany*’ or a time to ‘*see the light*’, leading to long-term contraception use, but this may not be the case for other women.

Successful behaviour change in the field of contraception is likely to be related to a range of factors, including those background, intrapersonal, interpersonal and situation factors proposed by Sheeran.(254)(52) According to the Subjective Expected Utility Theory, the basis of most decision-making models introduced in Section 1.1, decision-making around post-abortion contraception is likely to involve weighing the costs and benefits of contraception use against those of a repeat pregnancy, factoring in the perceived likelihood of getting pregnant.(50) The challenge of sustaining behaviour change is particularly relevant for short-acting contraception methods like the daily oral contraceptive that require continued behaviour compared to long-acting methods like the intra-uterine device and could be explored in future studies.

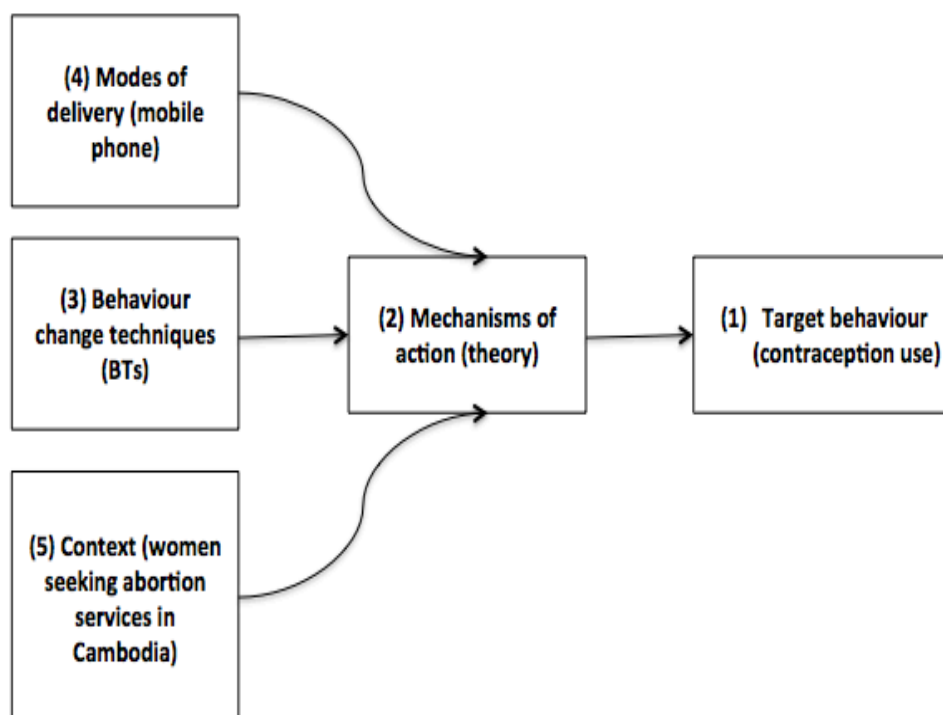
Mechanism of action of intervention

The mixed methods process evaluation presented in Chapters 6 to 7 provided additional insights into the mechanism by which the intervention resulted in behaviour change and how it was perceived by the women. The mechanism by which the intervention resulted in behaviour change can be considered in terms of the different components of Michie's scheme for a simple behaviour ontology introduced in Chapter 1, shown again here in Figure 54.

Mode of delivery

The mode of delivery was interactive voice messages and counsellor support delivered by mobile phone. Many of the women interviewed reported that support by mobile phone was a convenient way to ask questions or get advice without going to a health centre. The interactive voice message appeared to act as a conduit for additional support rather than directly influencing behaviour change, but may have promoted

Figure 54: Scheme for a simple behaviour ontology



engagement in the intervention. The review comparing one-way versus two-way text messaging discussed in Section 1.4 found that two-way messaging was more effective, although the identified trials also involved phone counselling.(129) Around half of the women that received the intervention actively requested to speak to a counsellor (pressed '1') and those who spoke to the counsellor having requested to (by pressing '1') were more likely to subsequently use effective contraception compared to women who didn't request or speak to the counsellor.

The majority of support for contraception use and other post-abortion issues appeared to be provided by the counsellor calls rather than the voice message.

There was evidence from interviews that the counselling provided support for *intrapersonal* determinants of contraceptive use, as defined in Sheeran's model, such as health concerns, fear or experience of side-effects.(52) Phone counselling enables more personalised support to be delivered as well as increased amount of content. Counsellors are able to assess particular concerns and tailor content accordingly in a way that is not possible with automated messages. As reported in the qualitative interviews, phone counselling enabled the counsellor to develop a relationship with the client and convey empathy and a sense of being cared for that would be harder to achieve with an automated message.

Behaviour change techniques

The intervention can also be characterised in terms of individual behaviour change techniques. Recoding the intervention using Abraham and Michie's typology in Chapter 7 suggested that the intervention likely included six behaviour change techniques; two related to the voice messages (*provide instruction*, and *prompt practice*) and four related to the counselling (*provide information about behaviour-*

health link, provide information on consequences, prompt barrier identification and provide general encouragement).⁽²²⁷⁾⁽¹⁰⁴⁾ The finding that the intervention included several behaviour change techniques is consistent with the previously discussed adherence research showing that multifaceted interventions are likely to be more effective compared to uni-faceted interventions.⁽¹³⁴⁾

Mechanism of action (theory)

The qualitative interviews provided insights regarding mechanisms of behaviour change which can be conceptualised in terms of the *capability, motivation* and *opportunity* components of Michie's COB-B 'behaviour system'.⁽¹⁰⁰⁾

Capability in the behaviour system refers to the individual's psychological and physical capacity to engage in the activity concerned and includes having the necessary knowledge and skills.⁽⁴⁹⁾ An example from the interviews where the intervention may have increased the women's capability to use contraception would be the provision of individualised information on contraceptive methods via phone counselling with women reporting increased knowledge.

Motivation in the behaviour system refers to those brain processes that energise and direct behaviour and includes habitual processes, emotional responding as well as analytical decision-making. It includes reflective processes (involving plans) and automatic processes (involving emotions and impulses).⁽⁴⁹⁾ An example from the interviews where the intervention may have increased the women's motivation to use contraception could be the counsellor emphasizing the importance of taking the pill regularly to avoid getting pregnant again leading to the women changing her habit (the behaviour change technique of 'providing information on consequences').

Opportunity in the behaviour system refers to factors that lie outside the individual that make the behaviour possible or prompt it and includes physical opportunities (such as time, financial resources and access) and social opportunities created by the cultural environment.(49) An example from the interviews where the intervention may have increased the women's opportunity to use contraception could be the provision of information on where to access contraception and available discounts.

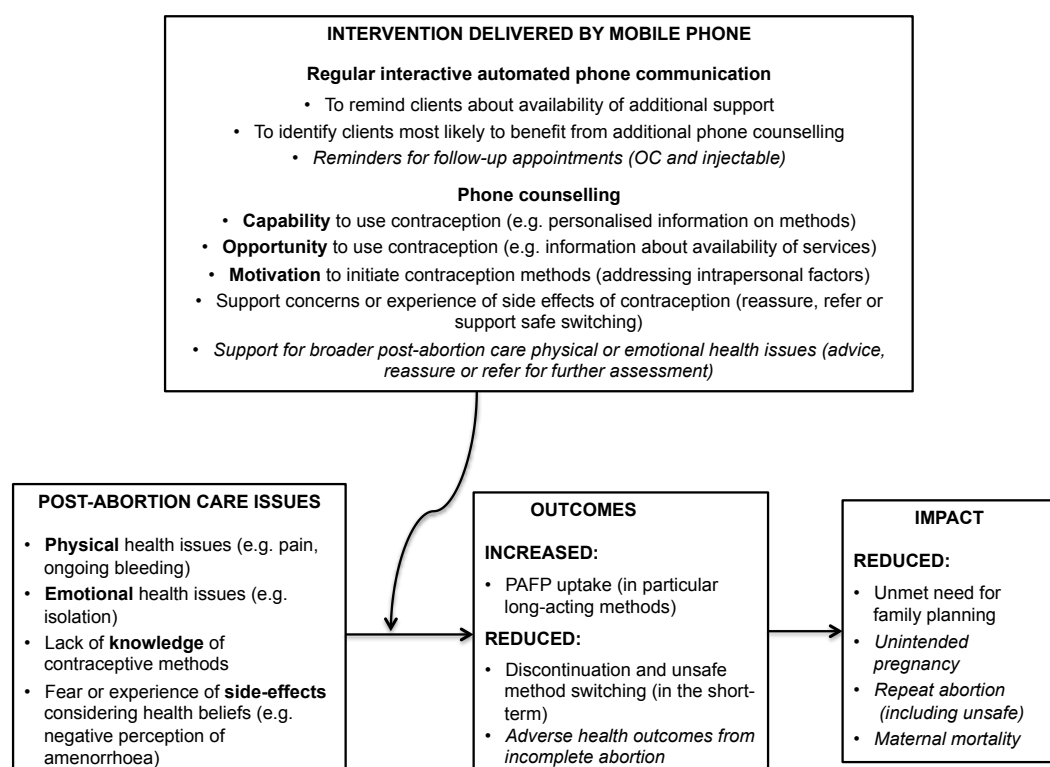
Updating the conceptual framework

Figure 55 shows an updated conceptual framework which seeks to better describe the intervention, based on findings from the trial and process evaluation. This framework could serve as a starting point for future intervention development for interventions delivered by mobile point to support post-abortion contraception.

Aspects of the conceptual framework *in italics* are more speculative and require further formative research. The main difference is that the updated conceptual framework includes broader post-abortion care (PAC), not limited to post-abortion family planning, as there was evidence that the intervention, in particular the phone counselling, provided support for additional physical and emotional issues.

When describing the intervention in this updated framework, the automated interactive message is separated from the phone counselling. The interactive message is considered a way of reminding clients about availability of support and a way to identify women most likely to benefit from additional support for contraception or other issues. It is not clear whether the pill or injectable reminder messages were effective and therefore this intervention component is in *italics*. Furthermore, there was insufficient evidence from the interviews that the intervention identified problems early. As the messages was sent to women ("push") every two weeks, and the majority

Figure 55: Updated conceptual framework



of calls were outgoing, it is not clear what women would do if they had a more urgent problem and therefore ‘identify problems early’ has been removed in the updated framework.

The phone counselling is expected to provide personalised support for clients to support contraception use and other post-abortion care issues. Phone counselling would aim to increase women’s capability, motivation and opportunity to use contraception.

In terms of outcomes and impact, the intervention could reduce unmet need for contraception by increasing uptake of long-acting methods, in particular IUD and implant. As these methods are associated with reduced discontinuation this might reduce unintended pregnancies and abortions over time although this was not demonstrated in our trial, perhaps due to lack of power. In the short-term the

intervention might reduce discontinuation and unsafe switching. The intervention might contribute towards reduced maternal mortality and morbidity through supporting broader physical and emotional issues but this requires further evaluation.

8.4 Implications for service delivery

Findings from this thesis have potential implications for service delivery and have been described in Chapters 5, 6 and 7.

Implementing the current intervention

Overall, the findings from this trial and process evaluation suggest that the intervention comprising six interactive voice messages +/- counsellor support for a range of contraceptive methods could be delivered as it was in the trial, at non-governmental clinics such as Marie Stopes International in Cambodia but further formative research is recommended prior to implementing similar interventions in other settings. Given that some women will choose to discontinue methods, the intervention should support use of a range of methods rather than focus on adherence to one particular method. The intervention might be expected to influence contraception use by increasing uptake of long-acting methods and increase safe-method switching during the three-month post-abortion period whilst the intervention is being delivered. After this time the effect of the intervention is likely to diminish and normal patterns of contraception discontinuation would be expected; with increased discontinuation of short-acting methods but less discontinuation of long-acting methods (IUD/implant). The intervention as implemented in the trial is likely to be positively received by most women as a convenient way to ask questions and get support for additional post-abortion physical and emotional issues without having to return to the clinic. The intervention could be offered to all women, with the

intervention likely to have greatest effect amongst women undecided about PAFP at the time of seeking abortion services. However, not all women are likely to want to enrol to receive the intervention, and amongst those that do, a minority are likely to find the voice messages intrusive. Although there were no reports of any adverse advents of the intervention, phone sharing is common in Cambodia and possible unintended consequences should be considered if someone other than the intended client answers a call.

Service providers would need to consider the cost-implications of implementing the intervention, balanced against potential benefits such as increased client loyalty and reputation of the organisation. It is unclear whether women would pay for the intervention and therefore the implementation costs would need to be budgeted by the organisation or a third-party funder. In contrast to the trial where women were recruited by research assistants, service providers or clinic staff would need to enrol women to the intervention, or at least obtain consent for a counsellor to call the women to enrol them to the intervention. The intervention for on-going support for post-abortion family planning should not distract from counselling and the opportunity to initiate contraceptive methods at the time of seeking abortion services.

Adapting the intervention

Findings from the process evaluation in Chapters 6 and 7 suggest several ways in which the intervention could be improved. The duration, language and mode of communication (i.e. text or voice) could be adapted to different settings, though voice messages will be most useful in populations with limited literacy. A longer intervention or a “booster” message at a later date could be evaluated. In settings where smartphone use is high, the intervention could be adapted whereby voice or text

messages are sent via an instant messaging application and listened to at the woman's convenience. This might increase the response rate to the messages. The content could be password protected, retained on the participants phone and listened to several times and shared with others if the participant wished. Use of such applications provides additional opportunities to add other low-literacy content such as stickers/cartoons and future research could evaluate such interventions.

Given that women were more likely to subsequently use contraception if they requested to speak to a counsellor (i.e. pressed '1'), the intervention could be further refined so that counsellors only phone women that request to speak to a counsellor.

As the cost of counselling is likely to be the main limitation to scaling up the intervention, this change would reduce costs but any effect of the intervention amongst women that speak to the counsellor *without* requesting a call would be lost.

Future interventions for post-abortion contraception could consider including messages to support comprehensive post-abortion care more broadly and should anticipate that women may have a range of issues and be prepared to manage these safely. Possible unintended consequences should be considered when developing future intervention content in settings where phone sharing is common. Some women will have repeat unintended pregnancies and counsellors should be prepared to provide advice on emergency contraception, where appropriate, or availability of safe-abortion services.

8.5 Recommendations for future research

Findings from this thesis have potential implications for future research and have been described in Chapters 5, 6 and 7.

Repeat systematic review

Subsequent to the publication of the systematic review of mobile phone-based interventions to improve contraception use (Chapter 2), one study has reported findings that would likely meet the inclusion criteria for the review; the evaluation of m4RH in Kenya, described in Section 2.8.(190) At the time of writing, other trials of interventions delivered by mobile phone are being conducted in Bangladesh, Palestine, Tajikistan and Bolivia. In the light of this emerging evidence, an update to the systematic review is recommended in one or two years. Future reviews could include trials using mobile phones for voice calls alone as well as non-trial mobile phone-based contraception initiatives and include a meta-analysis comparing automated interventions with those that include phone counselling.

Trials

Future studies could assess similar interventions delivered by mobile phone to increase contraception use including more automated interventions, interventions delivered by smartphone as outlined above or the effect of varying the duration of the intervention. Larger studies could be powered to detect differences in repeat pregnancy and repeat abortion. Objective measures of contraception use such as use of electronic monitoring devices should be considered if appropriate (discussed in section 5.7). Attempts could be made to measure additional use of services resulting from participants sharing intervention content with other people such as family and friends (discussed in Chapter 7). Future studies could assess interventions to increase contraception use and support post-abortion care more broadly and could assess health outcomes related to post-abortion care. Interventions should be clearly described and process evaluations conducted to gain insights into their mechanism of action.

As discussed in Chapter 5, most women participating in the MOTIF trial were married, multiparous, had attended secondary school, were aged over 25 years and had paid for reproductive health services at a clinic run by a nongovernmental organisation. The effect of interventions delivered by mobile phone on PAFP amongst youth and marginalised populations such as sex workers, known to have high unmet need for contraception and a high abortion rate,(91) requires further evaluation. Future research could assess the effect of similar interventions in settings with more limited support: for example, where medical abortions are provided by the private sector. Recruitment of participants might be more challenging in this setting, but important given the trend towards medical abortion in Cambodia and globally.(74)(20) Trials assessing longer term outcomes or with younger populations or those of lower socio-economic status might expect increased attrition and require imputation of outcome data.

Finally, further research is required on cost-effectiveness and sustainability models of interventions delivered by mobile phone to increase contraception use. In addition to the planned cost-effectiveness of the MOTIF trial, operational research could examine clients' actual willingness to pay for such interventions.

8.6 Conclusions

With reference to the over-arching research question, findings from this thesis suggest that interventions delivered by mobile phone can increase contraception use, but the evidence to date is mixed.

The trials identified in a systematic review reporting increased contraceptive use were more complex; one involving a range of educational text messages and the MOBILE Technology for Improved Family Planning (MOTIF) trial comprising interactive voice

messages with counsellor support. The MOTIF intervention was associated with increased self-reported use of effective contraception at four months post-abortion but not at 12 months, but use of long-acting contraception (IUD, implant, permanent method) was increased at four and 12 months. The intervention effect was primarily due to increased initiation of long-acting methods whilst receiving the intervention over the three-month post-abortion period; and appear to support aspects of the original study hypothesis that *'the intervention will remind clients about contraceptive methods available, identify problems with side effects early and provide appropriate support, and will boost motivation to use PAFP, while reducing discontinuation and unsafe method switching'* as summarised in the conceptual framework. Process evaluation findings indicated that the intervention provided support for post-abortion care more broadly. Women were more likely to request to speak to a counsellor if they were of lower socio-economic status or increased parity which suggests that the intervention is equitable in terms of engaging those most in-need and could have public health benefits at scale. The MOTIF intervention could be implemented in current form, however cost-effectiveness analysis is still ongoing. The intervention could potentially be improved so that counsellors only phone women that request to speak to the counsellor, and the duration and mode of communication could be adapted to different settings. Further high-quality adequately powered trials of interventions delivered by mobile phone to increase contraception use are required.

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9. APPENDICES

Appendix 1: Additional outputs & dissemination

In addition to submission of papers to open-access peer-reviewed journals, additional dissemination of this research has included:

Conference presentations

- **Society of Academic Primary Care (SAPC) Annual Scientific Meeting**, *'Effects of a mobile phone-based intervention to support post-abortion family planning in Cambodia'*, 10/7/15
- **UCL Global mHealth conference 2015**, *'Effect of a mobile phone-based intervention to support post-abortion family planning'*, 28/1/2015
- **Global mHealth forum 2014**, Washington DC, *'Mobile Technology for Improved Family Planning (MOTIF)'*, 10/12/14
- **International Conference on Family Planning 2013**, Ethiopia, *'Development of the MOTIF intervention'*, 2013

Presentations at other meetings

- **'Contraception after medical abortion meeting'**, Santa Monica, *'Effect of a mobile phone-based intervention on post-abortion contraception in Cambodia'*, March 2016
- **Post-abortion care (PAC) consortium meeting** (linked to ICFP 2016, Indonesia), *'Effect of a mobile phone-based intervention on post-abortion contraception in Cambodia'*, 23/1/16
- **Research dissemination presentation** to LSHTM alumni Cambodia (25/2/15)
- **Research dissemination webinar** to MSI Pakistan and other country programmes, 5/11/14
- **Research dissemination presentation** to Marie Stopes International London staff, 3/11/14
- **Research dissemination presentation** to MSI USA staff, Washington DC, 10/12/14
- **WHO health partners meeting**, Cambodia, research dissemination presentation, 28/8/14
- **Research dissemination presentation** to MSI Vietnam office staff, Hanoi, 14/8/14

Internal presentations at LSHTM

- **Abortion related research: where are we at and where are the gaps?**, LSHTM seminar presentation, *'Effect of a mobile phone-based intervention on post-abortion contraception in Cambodia'*, 20/6/16
- **Feedback from the International Conference on Family Planning**, presentation at MARCH seminar, 4/2/16

- **Presentation to clinical trials unit ‘critical mass’ meeting**, ‘Effect of a mobile phone-based intervention on post-abortion contraception in Cambodia’, 23/1/15
- **Presentation to MARCH seminar** at LSHTM, ‘Effect of a mobile phone-based intervention on post-abortion contraception in Cambodia; methodological issues’, 26/1/15
- **Presentation at MARCH seminar**, ‘Loss to follow up and dealing with missing data in contraception trials: experience from the MOBILE Technology for Improved Family Planning (MOTIF) trial’, 1/10/15

Other media

- **Interviewed** for New Scientist article ‘Women in Oregon can now get the pill over the counter’ (5 January 2016): <https://www.newscientist.com/article/dn28726-women-in-oregon-can-now-get-the-pill-over-the-counter/>
- **Interviewed** for Phnom Penh Post article ‘Kingdom’s contraception demand ‘unmet’ (31 Dec 2015): <http://www.phnompenhpost.com/national/kingdoms-contraception-demand-unmet>
- **Video** ‘How Marie Stopes International Uses Verboice to Deliver Sexual Health Information in Cambodia’ (2015): <http://www.ilabsoutheastasia.org/news-media/video/how-marie-stopes-international-uses-verboice-to-deliver-sexual-health-information-in-cambodia/>
- **Interviewed** for Medical Research Council network publication ‘Mobile medicine’ (Winter 2014/15): <https://www.mrc.ac.uk/news/magazine/network-winter-2014-15/>
- **Interviewed** for Phnom Penh Post article ‘On the phone’ (31 Jan 2014): <http://www.phnompenhpost.com/7days/phone>
- **Facilitated session of ‘Talent Development Program’** to build capacity for young talent in ICT and technology in Cambodia, USAID Cambodia Development Innovations Project, Cambodia, 15/9/14
- Provided informal advice to the following PhD students working on e/mHealth and sexual and reproductive health: Kate Reiss (LSHTM), Ona McCarthy (LSHTM), Emma Wilson (LSHTM/Kings), Emma Rezel (Kings/LSHTM), Sharmani Barnard (Kings/LSHTM)
- Preparation of study newsletters, research summary documents, and reports for Marie Stopes International

During my PhD I have undertaken the following research training:

- **Analysing Survey and Population Data** (attended lectures), 2016
- **STATA programming: creating beautiful tables**, LSHTM, Sept 2015
- **MRC fellows induction workshop**, MRC, April 2015
- **Producing a research poster**, LSHTM, 8/1/15
- **Demographic methods** (attended lectures/practicals), Oct/Nov 2014


- **Writing for non-scientific audiences** (MRC workshop), 1/10/14
- **Introduction to STATA**, LSHTM, Feb 2014
- **Statistical Methods for Epidemiology**, LSHTM, (D/L), 2013
- **Introduction to Good Clinical Practice (GCP)**, 2012

I (or my research team) have won or been shortlisted for the following awards:

- 120 under 40: The New Generation of Family Planning Leaders, Nominee, 2016
- Max Perutz Science Writing Award shortlist: *'Mobile phones for family planning'*, 2014
- MRC Population Scientist Fellowship, 2014
- 2014 Communication for Social Change Award, University of Queensland. Marie Stopes International MOTIF project. Finalist // Cambodia, 2014
- Marie Stopes CEO pick of Innovation Fund projects for MOTIF project, 2013

Appendix 2: Ethical approvals

Figure 56: Ethical approval for formative research (NECHR)


ក្រសួងសុខាភិបាល
MINISTRY OF HEALTH
គណៈកម្មាធិការជាតិស្រាវជ្រាវស្វែងរក
សំរាប់ការស្រាវជ្រាវសុខភាពដែលទាក់ទងនឹងមនុស្ស
National Ethics Committee for Health Research
លេខ...១២៣...NECHR

ព្រះរាជាណាចក្រកម្ពុជា
KINGDOM OF CAMBODIA
ជាតិ សាសនា ព្រះមហាក្សត្រ
NATION RELIGION KING
រាជធានីភ្នំពេញ, ថ្ងៃទី...២០...ខែ...១០...ឆ្នាំ២០១២

Dr. Chris Smith

Project: MObile Technology for Improved Family Planning services: The development, piloting and evaluation of a mobile phone-based intervention to support use of post-abortion contraception in Cambodia. Version N° 1, date 5th October 2012.

Reference: 26th October, 2012 NECHR meeting minute

Dear Dr. Chris Smith,

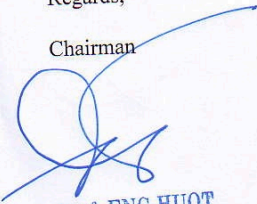
I am pleased to notify you that your study protocol entitled “MObile Technology for Improved Family Planning services: The development, piloting and evaluation of a mobile phone-based intervention to support use of post-abortion contraception in Cambodia. Version N° 1, date 5th October 2012” has been approved by National Ethic Committee for Health Research (NECHR) in the meeting on 26th October, 2012. This approval is valid for twelve months after the approval date.

The Principal Investigator of the project shall submit following document to the committee’s secretariat at the National Institute of Public Health at #2 Kim Il Sung Blvd, Khan Tuol Kok, Phnom Penh. (Tel: 855-23-880345, Fax: 855-23-881949):

- Annual progress report
- Final scientific report
- Patient/participant feedback (if any)
- Analyzing serious adverse events report (if applicable)

The Principal Investigator should be aware that there might be site monitoring visits at any time from NECHR team during the project implementation and should provide full cooperation to the team.

Regards,

Chairman

Prof. ENG HUOT

លេខ ២ មហាវិថី គីម អ៊ីលសុង, ខណ្ឌទួលគោក, រាជធានីភ្នំពេញ, ទូរស័ព្ទ (៨៥៥-២៣) ៨៨០ ៣៤៥, ទូរស័ព្ទដៃ (៨៥៥-១២) ២៨០ ៧៩០, (៨៥៥-១២) ៨៨២ ៤៤២
2 Blvd KIM YL SUNG, Khan Toul Kork, Phnom Penh, Tel : (855-23) 880 345, Mobile phone : (855-12) 280 790, (855-12) 842 442

Figure 57: Ethical approval for formative research (LSHTM)

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk



Observational / Interventions Research Ethics Committee

Chris Smith
Research Student
DPH/EPH
LSHTM

26 October 2012

Dear Dr Smith,

Study Title: MOTIF: MOBILE Technology for Improved Family Planning Services
LSHTM ethics ref: 6282

Thank you for your email of 24 October 2012, responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
LSHTM ethics application	V2	
Protocol, including Information Sheet and Consent form	V4	October 2012

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form. All studies are also required to notify the ethics committee of any serious adverse events which occur during the project via form E4. An annual report form (form E3) is required on the anniversary of the approval of the study and should be submitted during the lifetime of the study. At the end of the study, please notify the committee via form E5.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Andrew J Hall', with a horizontal line underneath.

Professor Andrew J Hall
Chair
ethics@lshtm.ac.uk
<http://intra.lshtm.ac.uk/management/committees/ethics/>

Figure 58: Ethical approval for formative research (MSI)



MSI Ethics Review Committee approval for application number 013-12-FT-A

Project Title: MOTIF: Mobile Technology for Improved Family Planning, Cambodia

Submitting Officer: Chris Smith

Approval Date: 17 Feb 2013

Dear Chris,

I am pleased to notify you that the above-titled protocol has been reviewed and approved by the independent Ethics Review Committee (ERC) of MSI. This approval is valid for 24 months after the approval date.

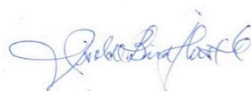
Please submit the following to the ERC, as and when appropriate:

- Final scientific report, or published paper
- Serious adverse events report (if applicable)
- A Change of Protocol form in the event of any modifications to the protocol reviewed by the ERC, before any such changes are implemented.
- A Continuing Review Application if the study continues beyond 24 months after the approval date.

We wish you the best of luck with your study.

Sincerely,

Signed:


A handwritten signature in blue ink, which appears to be 'Deputy Chair', is located below the 'Signed:' text.

Deputy Chair, MSI ERC

Date: 17 Feb 2013

Also reviewed by: Marika McAdam

Figure 59: Ethical approval for trial (NECHR)



ក្រសួងសុខាភិបាល
MINISTRY OF HEALTH
គណៈកម្មាធិការជាតិរៀបចំការស្រាវជ្រាវ
សម្រាប់ការស្រាវជ្រាវសុខភាពដែលទាក់ទងនឹងមនុស្ស
National Ethics Committee for Health Research

ព្រះរាជាណាចក្រកម្ពុជា
KINGDOM OF CAMBODIA
ជាតិ សាសនា ព្រះមហាក្សត្រ
NATION RELIGION KING

លេខ...0192...N.E.C.H.R

រាជធានីភ្នំពេញ, ថ្ងៃទី ២០ ខែ ០៦ ឆ្នាំ ២០១៤

Dr. Chris Smith

Project: Request for continuing the protocol entitled “MOTIF: MOBILE Technology for Improved Family Planning services: The development, implementation and evaluation of a mobile phone-based intervention to support use of post-abortion contraception in Cambodia. Version N° 1, dated 8th February 2013”

Reference: 27th June, 2014 NECHR meeting minute

Dear Dr. Chris Smith,

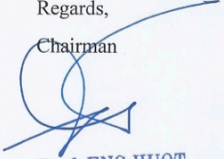
I am pleased to inform you that your request for continuing of your study protocol entitled “MOTIF: MOBILE Technology for Improved Family Planning services: The development, implementation and evaluation of a mobile phone-based intervention to support use of post-abortion contraception in Cambodia. Version N° 1, dated 8th February 2013” has been approved by National Ethic Committee for Health Research (NECHR) in the meeting on 27th June, 2014 NECHR. This approval is valid for twelve months after the approval date.

The Principal Investigator of the project shall submit following document to the committee’s secretariat at the National Institute of Public Health at #2 Kim Il Sung Blvd, Khan Tuol Kok, Phnom Penh. (Tel: 855-23-880345, Fax: 855-23-881949):

- Annual progress report
- Final scientific report
- Patient/participant feedback (if any)
- Analyzing serious adverse events report (if applicable)

The Principal Investigator should be aware that there might be site monitoring visits at any time from NECHR team during the project implementation and should provide full cooperation to the team.

Regards,



Chairman

Prof. ENG HUOT

លេខ ២ មហាវិថី ពីម អ៊ុលសុង . ខណ្ឌទួលគោក . រាជធានីភ្នំពេញ . ទូរស័ព្ទ (៨៥៥-២៣) ៨៨០ ៣៤៥ . ទូរស័ព្ទដៃ (៨៥៥-១២) ២៨០ ៧៩០ . (៨៥៥-១២) ៨៤២ ៤៤២
 # 2 Blvd KIM YL SUNG, Khan Toul Kork, Phnom Penh , Tel : (855-23) 880 345 , Mobile phone : (855-12) 280 790, (855-12) 842 442 *

Figure 60: Ethical approval for trial (LSHTM)

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk



Observational / Interventions Research Ethics Committee

Chris Smith
Research Degree Student
DPH / EPH
LSHTM

23 August 2013

Dear Dr. Smith,

Study Title: MOTIF: MObile Technology for Improved Family Planning Services
LSHTM ethics ref: 6378
LSHTM amend no: A440

Thank you for your email of 21 August 2013, responding to the Interventions Committee's request for further information on the above amendment to research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
LSHTM amendment application	n/a	
Protocol	v4	July 2013

After ethical review

Any further changes to the application must be submitted to the Committee via an E2 amendment form. The Principal Investigator is reminded that all studies are also required to notify the ethics committee of any serious adverse events which occur during the project via form E4. An annual report form (form E3) is required on the anniversary of the approval of the study and should be submitted during the lifetime of the study. At the end of the study, please notify the committee via form E5.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'John Porter'.

Professor John DH Porter
Chair
ethics@lshtm.ac.uk
<http://intra.lshtm.ac.uk/management/committees/ethics/>

Figure 61: Ethical approval for trial (MSI)



MSI Ethics Review Committee approval for application number 002-13-E

Project Title: MObile Technology for Improved Family Planning Services – Phase 2

Submitting Officer: Chris Smith

Approval Date: 28 Feb 2013

Dear Chris,

I am pleased to notify you that the above-titled protocol has been reviewed and provisionally approved by the independent Ethics Review Committee (ERC) of MSI. This approval is conditional upon approval by an ethics committee in the host country and valid for 24 months after the approval date.

Please submit the following to the ERC, as and when appropriate:

- Proof of approval by a local ethics committee (if not already provided)
- Final scientific report, or published paper
- Serious adverse events report (if applicable)
- A Change of Protocol form in the event of any modifications to the protocol reviewed by the ERC, before any such changes are implemented.
- A Continuing Review Application if the study continues beyond 24 months after the approval date.

We wish you the best of luck with your study.

Sincerely,

Signed:


Date: 28 Feb 2013

A handwritten signature in blue ink, appearing to read 'Julia Benfield', is written over a faint circular stamp.

Deputy Chair, MSI ERC

Also reviewed by: Marika McAdam

Figure 62: Ethical approval for 12-month follow up (NECHR)



ក្រសួងសុខាភិបាល
MINISTRY OF HEALTH
គណៈកម្មាធិការជាតិរៀបចំការស្រាវជ្រាវ
សំរាប់ការស្រាវជ្រាវសុខភាពដែលទាក់ទងនឹងមនុស្ស
National Ethics Committee for Health Research

ព្រះរាជាណាចក្រកម្ពុជា
KINGDOM OF CAMBODIA
ជាតិ សាសនា ព្រះមហាក្សត្រ
NATION RELIGION KING

លេខ...0192...N.E.C.H.R

រាជធានីភ្នំពេញ, ថ្ងៃទី ២០ ខែ ០៦ ឆ្នាំ ២០១៤

Dr. Chris Smith

Project: Request for continuing the protocol entitled “MOTIF: MOBILE Technology for Improved Family Planning services: The development, implementation and evaluation of a mobile phone-based intervention to support use of post-abortion contraception in Cambodia. Version N° 1, dated 8th February 2013”

Reference: 27th June, 2014 NECHR meeting minute

Dear Dr. Chris Smith,

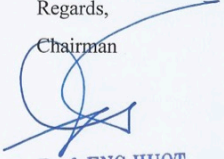
I am pleased to inform you that your request for continuing of your study protocol entitled “MOTIF: MOBILE Technology for Improved Family Planning services: The development, implementation and evaluation of a mobile phone-based intervention to support use of post-abortion contraception in Cambodia. Version N° 1, dated 8th February 2013” has been approved by National Ethic Committee for Health Research (NECHR) in the meeting on 27th June, 2014 NECHR. This approval is valid for twelve months after the approval date.

The Principal Investigator of the project shall submit following document to the committee’s secretariat at the National Institute of Public Health at #2 Kim Il Sung Blvd, Khan Tuol Kok, Phnom Penh. (Tel: 855-23-880345, Fax: 855-23-881949):

- Annual progress report
- Final scientific report
- Patient/participant feedback (if any)
- Analyzing serious adverse events report (if applicable)

The Principal Investigator should be aware that there might be site monitoring visits at any time from NECHR team during the project implementation and should provide full cooperation to the team.

Regards,



Chairman

Prof. ENG HUOT

លេខ ២ មហាវិថី ពីម អ៊ុលសុង . ខណ្ឌទួលគោក . រាជធានីភ្នំពេញ . ទូរស័ព្ទ (៨៥៥-២៣) ៨៨០ ៣៤៥ . ទូរស័ព្ទដៃ (៨៥៥-១២) ២៨០ ៧៩០ . (៨៥៥-១២) ៨៨២ ៤៤២
2 Blvd KIM YL SUNG, Khan Toul Kork, Phnom Penh , Tel : (855-23) 880 345 , Mobile phone : (855-12) 280 790, (855-12) 842 442 *

Figure 63: Ethical approval for 12-month follow up

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk



Observational / Interventions Research Ethics Committee

Dr. Christopher Smith
DPH / EPH
LSHTM

8 July 2014

Dear Dr. Smith,

Study Title: MOTIF: MOBILE Technology for Improved Family Planning

LSHTM Ethics Ref: 6378-01

Thank you for your application of 12 June 2014 for the above amendment to the existing ethically approved study and submitting revised documentation. The amendment application has been considered by the Interventions Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Other	Form E2 amendment for MOTIF project 6378.docx	29/07/2013	Amendment Jul 2013
Other	Phase 2 MOTIF trial protocol v5 LSHTM amendment.docx	12/06/2014	5

After ethical review

Any further changes to the application must be submitted to the Committee via an Amendment form on the ethics online applications website. The Principal Investigator is reminded that all studies are also required to notify the ethics committee of any serious adverse events which occur during the project via an Adverse Event form on the ethics online applications website. An annual report form is required on the anniversary of the approval of the study and should be submitted during the lifetime of the study on the ethics online applications website. At the end of the study, please notify the committee via an End of Study form on the ethics online applications website. Ethics online applications website link: <http://leo.lshtm.ac.uk>

Yours sincerely,

A handwritten signature in black ink, appearing to read 'John Porter'.

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
<http://www.lshtm.ac.uk/ethics/>

Improving health worldwide

Figure 64: Ethical approval for 12-month follow up (MSI)



MSI Ethics Review Committee approval for application number 002-13-Am14

Project Title: MOTIF:MOBILE Technology for Improved Family Planning

Submitting Officer: Chris Smith

Approval Date: 4 July 14

Dear Chris,

I am pleased to notify you that the above-titled protocol has been reviewed and approved by the independent Ethics Review Committee (ERC) of MSI. This approval is conditional upon approval by an ethics committee in the host country. The ERC's approval is valid for 12 months after the approval date.

Please submit the following to the ERC, as and when appropriate:

- Proof of approval by a local ethics committee (if not already provided)
- Final scientific report, or published paper
- Incident form (if applicable)
- An Amendment Form in the event of any modifications to the protocol reviewed by the ERC, before any such changes are implemented.
- A Continuing Review Application if the study continues beyond 12 months after the approval date.

We wish you the best of luck with your study.

Sincerely,

Signed:

Date: 4 July 14

A handwritten signature in blue ink, appearing to read 'Marika McAdam', is written over a faint, circular official stamp.

Marika McAdam

Co-Chair, MSI ERC

Appendix 3: Study consent forms and questionnaires

Figure 65: Participant information sheet for interview

Participant's Information Sheet for Interview
<p>We are inviting you to take part in a research study. Before you decide whether or not to participate, it is important that you know why we are doing the study and what is involved. Please read the following information carefully. If you are unable to read it we will read it to you.</p>
<p>What is the study?</p> <p>We are asking Marie Stopes service users to help us develop a mobile phone-based service to support contraception use for women who have recently had an abortion. We would like to ask your views in order to develop this service.</p>
<p>Why are we doing the study?</p> <p>We want to find out if a mobile phone-based service to support contraception use for women who have recently had an abortion can be supportive and acceptable.</p>
<p>Why have I been chosen?</p> <p>You have attended the MSI clinic, which provides abortion and other reproductive health services for women.</p>
<p>Do I have to take part?</p> <p>No, it is up to you to decide whether to take part.</p>
<p>What will happen if I take part?</p> <p>The researcher will arrange a time for an interview. We will ask you about your reasons for deciding to have an abortion, previous contraceptive use, views on the Marie Stopes service, your mobile phone usage, and views on the proposed intervention. With your permission, we will record the interview. The interview will take about an hour. With your permission we will contact you by phone one month after the interview to ask about your current use of contraception, and subsequently by email or phone according to your preference, to ask for your feedback about any new messages developed after the interview.</p>
<p>Will you recompense me for the time this takes?</p> <p>We will give you \$5 to cover travel expenses to attend the interview. We will give you \$5 to cover the expenses of giving feedback on any new messages developed after the interview.</p>
<p>What do I have to do? If you agree to take part you will need to and sign the consent form.</p>
<p>What are the alternatives? You do not have to take part. It will not affect any of the services that you receive</p>
<p>What are the possible disadvantages in taking part?</p> <p>The study will take some of your time. We cannot promise that your health will benefit.</p>
<p>What are the possible benefits of taking part?</p> <p>Your views can affect the information and support service users receive.</p>
<p>What will happen if I don't want to carry on with the study?</p> <p>You can withdraw from the study at any time by letting the researcher conducting the interview know and the data collected from you will not be used</p>
<p>What if there is a problem?</p> <p>You can discuss this with the researcher present or call us on xxxxxxx. If you want to make a complaint, please call us. If you would like to make a formal complaint write to Dr. Chris Smith who will follow the complaints procedure.</p>
<p>Will my taking part in this study be kept confidential?</p> <p>Yes. Your comments will be identified by a research number only and all your comments will be made anonymous.</p>
<p>What will happen to the results of the research study?</p>

We will use your views to develop the mobile phone-based service. Once we have developed a mobile phone-based service that service users like and find helpful we will test them on a larger group of service users to see if they can improve contraception use after an abortion.

Who is organising and funding the research?

The study is being run by: Dr. Chris Smith (lead investigator), a collaboration between Marie Stopes International and the University of London. Marie Stopes International is funding the study.

Who has reviewed the trial?

The London School of Hygiene and Tropical Medicine (LSHTM) ethics committee, Marie Stopes International Ethics Committee, Cambodia Ethics Committee

The team contact details: Tel xxxxxxxxxxxx **email:** chris.smith@xxxxxxxxxx, LSHTM , Keppel St, London, WC1E 7HT

Thank you for taking the time to consider taking part.

If you would like further information please speak to the research present or ring the study team on xxxxxxxxxxxx

Figure 66: Participant information sheet for focus group

Participant's Information Sheet for Focus Group

We are inviting you to take part in a research study. Before you decide whether or not to participate, it is important that you know why we are doing the study and what is involved. Please read the following information carefully. If you are unable to read it we will read it to you.

What is the study?

We are asking Marie Stopes service users to help us develop a mobile phone-based service to support contraception use for women who have recently had an abortion. We would like to ask your views about what should be in the messages. We would like your help and comments to make the messages supportive, helpful and easy to understand.

Why are we doing the study?

We want to find out if a mobile phone-based service to support contraception use for women who have recently had an abortion can be supportive and acceptable.

Why have I been chosen?

You have attended the MSI clinic, which provides abortion and other reproductive health services for women.

Do I have to take part?

No, it is up to you to decide whether to take part.

What will happen if I take part?

The researcher will arrange a time for a group discussion. Groups will comprise clinic staff and around four service users. We will ask you about your mobile phone usage, and views on the proposed intervention and messages developed.

With your permission, we will record the group discussion. The discussion will take about an hour. With your

permission we will contact you (by email or phone according to your preference) to ask for your feedback about any new messages developed after the discussion.

Will you recompense me for the time this takes?

We will give you \$5 to cover travel expenses to attend. We will give you \$5 to cover the expenses of giving feedback on any new messages developed after the meeting.

What do I have to do? If you agree to take part you will need to and sign the consent form.

What are the alternatives? You do not have to take part. It will not affect any of the services that you receive

What are the possible disadvantages in taking part?

The study will take some of your time. We cannot promise that your health will benefit.

What are the possible benefits of taking part?

Your views can affect the information and support service users receive.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time by letting the researcher conducting the group discussion know and the data collected from you will not be used.

What if there is a problem?

You can discuss this with the researcher present or call us on xxxxxxx. If you want to make a complaint, please call us. If you would like to make a formal complaint write to Dr. Chris Smith who will follow the complaints procedure.

Will my taking part in this study be kept confidential?

Yes. Your comments will be identified by a research number only and all your comments will be made anonymous.

What will happen to the results of the research study?

We will use your views to develop the mobile phone-based service. Once we have developed a mobile phone-based service that service users like and find helpful we will test them on a larger group of service users to see if they can improve contraception use after an abortion.

Who is organising and funding the research?

The study is being run by: Dr. Chris Smith (lead investigator), a collaboration between Marie Stopes International and the University of London. Marie Stopes International is funding the study.

Who has reviewed the trial?

The London School of Hygiene and Tropical Medicine (LSHTM) ethics committee, Marie Stopes International Ethics Committee, Cambodia Ethics Committee

The team contact details: Tel xxxxxxxxxxx email: chris.smith@xxxxxxxxxxx, LSHTM , Keppel St, London, WC1E 7HT

Thank you for taking the time to consider taking part.

If you would like further information please speak to the research present or ring the study team on xxxxxxxxxxx

Figure 67: Consent form for interview

Consent Form for Interview
<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> <p>MOTIF: MOBILE Technologies for Improved Family Planning</p> <p>Developing a mobile phone-based post-abortion contraception service</p> </div>
<p>I _____ have read and understood the participants' information sheet (or it has been read to me). You have explained what you are trying to find out and why you would like to talk to me.</p> <p>Please put a mark in the box to the right if you think the sentence is true:</p> <p>I have asked all the questions that I need to and I am happy with the answers you have given me.</p> <p>I allow you to write about what I have said during our talk and I understand that you won't be using my real name.</p> <p>I understand that I don't have to talk about things that I don't want to talk about. I know that I can stop our talk at any time and without giving a reason for this and the data collected from me will not be used</p> <p>I am happy for you to record our talk.</p> <p>I am happy for you to contact me by phone one month after the interview to ask me about my current contraceptive use</p> <p>I understand that I can take a look at the draft report for this study if I want to.</p> <p>I would like to take part in the study. I can still change my mind at any time.</p>

My questions have been answered by _____

Participant (name in BLOCK CAPITALS) _____

Telephone number _____

Signed _____

Date _____

Researcher (name in BLOCK CAPITALS) _____

Signed _____

Date _____

If you need more information to help you decide, call xxxxxxxxxx email chris.smith@xxxxxxxxxxx

Figure 68: Consent form for focus group

Consent Form for Focus Group

I _____ have read and understood the participants' information sheet (or it has been read to me). You have explained what you are trying to find out and why you would like to talk to me.

Please put a mark in the box to the right if you think the sentence is true:

MOTIF: MOBILE Technologies for Improved Family Planning

Developing a mobile phone-based post-abortion contraception service

I have asked all the questions that I need to and I am happy with the answers you have given me.	-
I allow you to write about what I have said during the group discussion and I understand that you won't be using my real name.	..
I understand that I don't have to talk about things that I don't want to talk about. I know that I can withdraw from the group discussion at any time and without giving a reason for this and the data collected from me will not be used	
I don't mind that you record the group discussion.	.
I understand that I can take a look at the draft report for this study if I want to.	.
I would like to take part in the study. I can still change my mind at any time.	..

My questions have been answered by _____

Participant (name in BLOCK CAPITALS) _____

Telephone number _____

Signed _____

Date _____

Researcher (name in BLOCK CAPITALS) _____

Signed _____

Date _____

If you need more information to help you decide, call xxxxxxxxxx email chris.smith@xxxxxxxxxxx

Figure 69: Participant information sheet for trial

Participant's Information Sheet for Trial

We are inviting you to take part in a research trial. Before you decide whether or not to participate, it is important that you know why we are doing the trial and what is involved. Please read the following information carefully. If you are unable to read it we will read it to you.

What is the study?

MOTIF is a mobile phone-based service for Marie Stopes service users who have recently had an abortion to support contraception use.

Why are we doing the study?

We want to find out if a mobile phone-based service to support contraception use for women who have recently had an abortion can be supportive, acceptable and effective.

Why have I been chosen?

You have attended the MSI clinic, which provides abortion and other reproductive health services for women.

Do I have to take part?

No, it is up to you to decide whether to take part.

What will happen if I take part?

The study team will phone you to collect some information. We will then put you into one of two groups by chance (randomly). One group will get the MOTIF (mobile phone-based service) and the other will not (the control group). Participants in the MOTIF group will receive a phone call within a few days to further introduce the service which will involve regular SMS, voice message or direct call communication to you according to your situation and preferences. Also, you will be able to contact the service for support. The control group will receive standard care. This includes face-to-face post-abortion counselling, follow-up at two weeks, the clinic phone number, and Hotline phone number for support. We will contact you in four months time by phone to find out what contraception you are using. We may ask you to return to the clinic for face-to-face follow up. We may also attempt to contact you after one year and two years to find out about contraception use and subsequent pregnancies/abortions.

What do I have to do?

If you agree to take part you will need to read the consent form (or have it read to you) and sign the consent form. The consent form does not have to be signed immediately. You can take your time before you decide whether to participate or not.

What are the alternatives?

You do not have to take part. It will not affect any of the services that you receive

What are the possible disadvantages in taking part?

The study will take some of your time. We cannot promise that your health will benefit. The support could make some participants aware that they are in abusive relationships. The service or research team will be able to provide information about how to access appropriate counselling services for people in abusive relationships.

What are the possible benefits of taking part?

Being involved in the trial will give you the chance to receive additional support for contraception and to reduce repeat abortion.

What happens when the research trial stops?

We will compare contraception use in the two different groups to see which group did better. If the MOTIF programme is effective, then we will consider conducting a larger study or providing the service more widely.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time by calling, texting, or emailing us

What if there is a problem?

Please call us and we will do our best to sort it out. If you would like to make a formal complaint write to Dr. Chris Smith who will follow the complaints procedure.

Will my taking part in this trial be kept confidential?

Yes.

What will happen to the results of the research study?

The results will be used to support post-abortion family planning for other clients. The results will be published in a scientific journal so that other doctors know about it. If you would like a copy of the results please contact us.

Will you recompense me for the time this takes?

We will give you \$4 to cover travel expenses if you are asked to attend for face-to-face follow up.

Who is organising and funding the research?

The study is being run by: Dr. Chris Smith (lead investigator), a collaboration between Marie Stopes International and the University of London. Marie Stopes International is funding the study.

Who has reviewed the trial?

The London School of Hygiene and Tropical Medicine (LSHTM) ethics committee, Marie Stopes International Ethics Committee, Cambodia Ethics Committee

The team contact details:

Tel xxxxxxxxxxxx email: chris.smith@xxxxxxxxxxx, LSHTM, Keppel St, London, WC1E 7HT

You should not use your phone while driving a vehicle

Thank you for taking the time to consider taking part.

If you would like further information please speak to the research present or ring the study team on XXXXXXXXXX

Figure 70: Consent form for trial (English version)

Consent Form for Trial	
<div style="border: 1px solid black; padding: 10px; margin: 0 auto; width: 80%;"> <p>MOTIF: MOBILE Technologies for Improved Family Planning Developing a mobile phone-based post-abortion contraception service</p> </div>	
<p>I _____ have read and understood the participants' information sheet (or it has been read to me). You have explained what you are trying to find out and why you would like me to participate in the trial.</p>	
<p>Please put a mark in the box to the right if you think the sentence is true:</p>	
I have asked all the questions that I need to and I am happy with the answers you have given me.	
I understand that there is only a 50% chance that I will receive the mobile phone-based service	
I allow you to contact me at four months by phone call to conduct a questionnaire and ask about my contraception use and views on the service	
I understand that some participants will be asked to attend the clinic for face-to-face follow up at four months	
I allow a member of clinic staff to view my clinic record and inform the research team about my contraception use (this only applies if I return for face-to-face follow up)	
I allow you to attempt to contact me after one and/or two years by phone call to ask about my contraception use	
I allow you to write about the communication between myself and the service and I understand that you won't be using my real name.	
I understand that I can request to withdraw from the study without giving a reason for this and additionally I can request the data collected from me will not be used	
I understand that I can take a look at the draft report for this study if I want to.	
I would like to take part in the study. I can still change my mind at any time.	
<p>My questions have been answered by _____</p> <p>Participant (name in BLOCK CAPITALS) _____</p> <p>Telephone number _____</p>	

Signed _____
Date _____
Researcher / clinic staff (name in BLOCK CAPITALS) _____
Signed _____
Date _____
If you need more information to help you decide, call XXXXXXXXXX email chris.smith@ XXXXXXXXXX

Figure 71: Participant information sheet for process evaluation (English version)

<p align="center">Participant's Information Sheet for Interview (process evaluation)</p> <p>We are inviting you to take part in an interview study. Before you decide whether or not to participate, it is important that you know why we are doing the study and what is involved. Please read the following information carefully. If you are unable to read it we will read it to you.</p> <p>What is the study?</p> <p>We are asking Marie Stopes service users who received the mobile phone-based (MOTIF) service for feedback to help us evaluate the service.</p> <p>Why are we doing the study?</p> <p>We want to find out if a mobile phone-based service to support contraception use for women who have recently had an abortion can be supportive and acceptable.</p> <p>Why have I been chosen?</p> <p>You received the mobile phone-based service to support post-abortion contraception.</p> <p>Do I have to take part?</p> <p>No, it is up to you to decide whether to take part.</p> <p>What will happen if I take part?</p> <p>The researcher will arrange a time for an interview. We will ask you about your contraception and mobile phone use, and views on the Marie Stopes MOTIF service. With your permission, we will record the interview. The interview will take about 30 minutes.</p> <p>Will you recompense me for the time this takes?</p> <p>We will give you \$4 to cover travel expenses to attend the interview.</p> <p>What do I have to do? If you agree to take part you will need to read the consent form (or have it read to you) and sign the consent form. The consent form does not have to be signed immediately. You can take your time before you decide whether to participate or not.</p> <p>What are the alternatives? You do not have to take part. It will not affect any of the services that you receive</p> <p>What are the possible disadvantages in taking part?</p> <p>The study will take some of your time. We cannot promise that your health will benefit.</p> <p>What are the possible benefits of taking part?</p> <p>Your views can affect the information and support service users receive.</p> <p>What will happen if I don't want to carry on with the study?</p> <p>You can withdraw from the study at any time by letting the researcher conducting the interview know and the data collected from you will not be used</p> <p>What if there is a problem?</p> <p>You can discuss this with the researcher present or call us on 089940679. If you want to make a complaint, please call us. If you would like to make a formal complaint write to Dr. Chris Smith who will follow the complaints procedure.</p> <p>Will my taking part in this study be kept confidential?</p> <p>Yes. Your comments will be identified by a research number only and all your comments will be made anonymous.</p>

What will happen to the results of the research study?

We will use your views to evaluate the mobile phone-based service. The results will be used to support post-abortion family planning for other clients. The results will be published in a scientific journal so that other doctors know about it. If you would like a copy of the results please contact us.

Who is organising and funding the research?

The study is being run by: Dr. Chris Smith (lead investigator), a collaboration between Marie Stopes International and the University of London. Marie Stopes International is funding the study.

Who has reviewed the trial?

The London School of Hygiene and Tropical Medicine (LSHTM) ethics committee, Marie Stopes International Ethics Committee, Cambodia Ethics Committee

The team contact details:

Tel XXXXXXXXXX email: chris.smith@XXXXXXXXXX, LSHTM, Keppel St, London, WC1E 7HT

Thank you for taking the time to consider taking part.

If you would like further information please speak to the research present or ring the study team on XXXXXXXXXX

Figure 72: Consent form for process evaluation interview (English version)

Consent Form for Interview	
<div style="border: 1px solid black; padding: 10px; margin: 0 auto; width: 80%;"> <p>MOTIF: MObile Technologies for Improved Family Planning Developing a mobile phone-based post-abortion contraception service</p> </div>	
<p>I _____ have read and understood the participants' information sheet (or it has been read to me). You have explained what you are trying to find out and why you would like to talk to me.</p>	
<p>Please put a mark in the box to the right if you think the sentence is true:</p>	
I have asked all the questions that I need to and I am happy with the answers you have given me.	<input type="checkbox"/>
I allow you to write about what I have said during our talk and I understand that you won't be using my real name.	<input type="checkbox"/>
I understand that I don't have to talk about things that I don't want to talk about. I know that I can stop our talk at any time and without giving a reason for this and the data collected from me will not be used	<input type="checkbox"/>
I am happy for you to record our talk.	<input type="checkbox"/>
I understand that I can take a look at the draft report for this study if I want to.	<input type="checkbox"/>
I would like to take part in the study. I can still change my mind at any time.	<input type="checkbox"/>
<p>My questions have been answered by _____</p> <p>Participant (name in BLOCK CAPITALS) _____</p> <p>Telephone number _____</p> <p>Signed _____</p> <p>Date _____</p> <p>Researcher (name in BLOCK CAPITALS) _____</p> <p>Signed _____</p> <p>Date _____</p> <p>If you need more information to help you decide, call XXXXXXXXXX email chris.smith@ XXXXXXXXXX</p>	

Figure 73: Trial registration form (English version)

Trial registration Form
<p>To be completed by either research assistant or clinic staff that have been given training. There is an additional form for baseline data collection because clinic staff will not have the time to collect detailed baseline data</p> <p><u>Part: 1 Eligibility</u></p> <ul style="list-style-type: none">• Purpose: to check eligibility <div><p>Client is eligible to participate in the trial:</p><ul style="list-style-type: none"><input type="checkbox"/> Client is aged 18 or over<input type="checkbox"/> Is attending for abortion<input type="checkbox"/> Doesn't want to have a child at the moment<input type="checkbox"/> Has a mobile phone<input type="checkbox"/> Is willing to provide informed consent</div> <p>If all boxes are checked then the client is eligible for the trial.</p> <ul style="list-style-type: none">• Provide 'Information for Participants' and obtain consent if the client wishes to proceed. Allow client to take time if required before providing consent. Offer client opportunity to discuss with research assistant on phone if appropriate. <p><u>Part 2: Contact details</u></p> <ul style="list-style-type: none">• Purpose: to collect contact details so that research assistant can contact client by phone to collect baseline data <div><p>Date / time:</p><p>Name:</p><p>Preferred name to use:</p><p>Mobile number(s):</p><p>Email:</p><p>Address:</p><p>Preferred time to contact:</p></div>

Figure 74: Trial baseline data collection form

4/11/2014

Edit form - [MOTIF Baseline Data collection form] - Google Forms

[google form upload](#)

This form will soon be upgraded to the new version of Google Forms. [Learn more.](#)

☐ Automatically collect respondent's Mariestopes International Cambodia username.

MOTIF Baseline Data collection form

You can include any text or info that will help people fill this out.

Clinic *

- ☐ CCA
- ☐ CTK
- ☐ CSR
- ☐ CBB

Name of RA *

Client ID (not name) *

How old were you at your last birthday? *

What is the highest level of school you have attended? *

- ☐ None
- ☐ Some primary
- ☐ Completed primary
- ☐ Some secondary
- ☐ Completed secondary
- ☐ More than secondary

What is your mother tongue language? *

- ☐ Khmer
- ☐ Vietnamese
- ☐ Chinese
- ☐ English
- ☐ Cham
- ☐ Other

"Can client point to numbers '1', '2', and '3' or their phone?" *

https://docs.google.com/a/mariestopes.org.kh/spreadsheets/gform?key=0ApiN_lA0dIxDdEFzRVN6YkVFOXl0dVcydkx3QWhoSmc&gridId=0#edit

1/5

- ☐ Cannot recognise all three numbers
- ☐ Able to recognise all three numbers

What is your occupation? *

- ☐ Factory worker
- ☐ Entertainment worker
- ☐ Farmer
- ☐ Housewife
- ☐ Employed
- ☐ Self-employed/own business
- ☐ Casual work/casual labour
- ☐ Unemployed
- ☐ Student
- ☐ Other

What is the highest value means of transport that you or your household own? *

- ☐ Car/van/truck/tractor
- ☐ Motorbike/motorcycle cart
- ☐ Bicycle/cyclo
- ☐ Oxcart/horsecart
- ☐ Boat with motor
- ☐ Boat without motor
- ☐ No means

How many living children do you have? ***Not including this abortion, how many previous induced abortions have you had in your lifetime? *****What was (is) the method used for your current abortion? ***

- ☐ Surgical
- ☐ Medical

Page 2

After page 1

[Continue to next page](#)**Did other people put pressure on you to have this abortion? ***

- ☐ No, not at all
- ☐ No, not really
- ☐ Yes, somewhat

☐ Yes, very much

Have you ever used any of the following contraceptive methods in the past?

Check box if yes

- ☐ Pill
☐ Injection
☐ Implant
☐ IUD/coil
☐ Condom

In the future, would you like to have (a/another) child, or would you prefer not to have any (more) children? *

- ☐ Have (an/another) child
☐ No more/none
☐ Undecided/don't know

Page 3

After page 2

[Continue to next page](#)*Note: "Go to page" selections will override this navigation. [Learn more.](#)***How long would you like to wait from now before the birth of (an/another) child?**

- ☐ Months
☐ Years
☐ After marriage
☐ Other
☐ Don't know

Page 4

After page 3

[Continue to next page](#)**Have you decided to start using a contraceptive method after this abortion? ***

- ☐ Yes
☐ No
☐ Undecided

Page 5

After page 4

[Continue to next page](#)*Note: "Go to page" selections will override this navigation. [Learn more.](#)***Which method?**

- ☐ Pill
☐ Injection

- ☐ Implant
- ☐ IUD/coil
- ☐ Permanent
- ☐ Condom
- ☐ Withdrawal
- ☐ Calender
- ☐ Other

[Text](#)

Page 6

After page 5

[Continue to next page](#)**What is your current marital status? ***

- ☐ Married or living together
- ☐ Divorced/separated
- ☐ Widowed
- ☐ Never married and never lived together (single)

Page 7

After page 6

[Continue to next page](#)*Note: "Go to page" selections will override this navigation. [Learn more.](#)***Are you still in a relationship with the person you became pregnant with? ***

- ☐ Yes
- ☐ No
- ☐ Not sure

Page 8

After page 7

[Go to page 9](#)**Would you say that using contraception is mainly your decision, mainly your (husband/partners) decision, or you you both decide together?**

- ☐ Mainly client
- ☐ Mainly husband/partner
- ☐ Joint decision
- ☐ Other

Page 9

After page 8

[Continue to next page](#)**How much credit do you usually have on your phone? ***

- ☐ I always have credit
- ☐ I usually have credit

☐ I sometimes have credit

Does anyone else ever use your phone? *

- ☐ Often
☐ Sometimes
☐ Rarely
☐ Never

Page 10

After page 9

[Continue to next page](#)

Note: "Go to page" selections will override this navigation. [Learn more.](#)

If yes, who?

- ☐ Husband/partner
☐ Mother
☐ Father
☐ Other relative/friend

Page 11

After page 10

[Continue to next page](#)

Does anyone else who uses your phone know about your abortion?

- ☐ Yes
☐ No

Page 12

After page 11

[Continue to next page](#)

Note: "Go to page" selections will override this navigation. [Learn more.](#)

First choice for contact *

8-10am ▾

Second choice for contact *

8-10am ▾

Third choice for contact *

8-10am ▾

Figure 75: 4-month trial follow up questionnaire

NAME OF PARTICIPANT:	TRIAL NUMBER:
<ol style="list-style-type: none"> 1. "Are you currently using a contraceptive method?" <ol style="list-style-type: none"> a. If YES, "which method (or methods) are you currently using?" 2. "Have you become pregnant again since having your abortion?" <ol style="list-style-type: none"> a. Yes b. No 3. Have you had another abortion since your abortion (four months ago)? <ol style="list-style-type: none"> a. Yes b. No 4. Have you had any involvement in road traffic accident as a result of mobile phone use? <ol style="list-style-type: none"> a. Yes b. No 5. Did anything happen to you as a consequence of participating in the trial, good or bad? <ol style="list-style-type: none"> a. None b. Argument c. Violence/domestic abuse d. Other 6. Did you know any other women who took part in the study (not a researcher)? <ol style="list-style-type: none"> a. Yes (if yes, provide details) b. No 7. Contraception use following abortion (complete table below) – week 1: "Did you start using a contraception method immediately after your abortion?". Continue for each week until the present time <p>Contraceptive discontinuation following abortion (complete table below). If the participant stopped using a method, ask why she stopped</p>	

DATE	WEEK SINCE ABORTION	1 REQUIRES A CODE FOR EVERY MONTH	2 CODE IF METHOD DISCONTINUED
	1		
	2		
	3		
	4		
	5		
	6		
	7		
	8		
	9		
	10		
	11		
	12		
	13		
	14		
	15		
	16		

COLUMN 1: CONTRACEPTIVE USE,
PREGNANCY, REPEAT ABORTION

0 NO METHOD
1 FEMALE STERILISATION
2 MALE STERILISATION
3 IUD/COIL
4 INJECTABLE

COLUMN 2: DISCONTINUATION OF CONTRACEPTIVE
USE

0 INFREQUENT SEX/HUSBAND/PARTNER
AWAY
1 BECAME PREGNANT WHILST USING
2 WANTED TO BECOME PREGNANT
3 HUSBAND/PARTNER DISAPPROVED

5 IMPLANT
 6 PILL
 7 CONDOM
 8 FEMALE CONDOM
 9 DIAPHRAGM
 J FOAM OR JELLY
 K LACTATONAL AMENORRHEA
 L RHYTHM METHOD
 M WITHDRAWAL
 X OTHER MODERN METHOD
 Y OTHER TRADITIONAL METHOD

4 WANTED MORE EFFECTIVE METHOD
 5 SIDE EFFECTS/HEALTH CONCERNS
 6 LACK OF ACCESS/TOO FAR
 7 COSTS TOO MUCH
 8 INCONVENIENT TO USE
 F UP TO GOD/FATALISTIC
 A DIFFICULT TO GET
 PREGNANT/MENOPAUSAL
 D MARITAL DISSOLUTION/SEPARATION
 X OTHER (SPECIFY)
 Z DON'T KNOW

P PREGNANCY
 A REPEAT ABORTION (INDUCED)
 M MISCARRIAGE

Figure 76: 12-month trial follow up questionnaire

Are you currently using a contraceptive method?				
Y	<input type="checkbox"/>	N	<input type="checkbox"/>	

If yes, which method are you using?				
	Pill	<input type="checkbox"/>		
	Injection	<input type="checkbox"/>		
	Implant	<input type="checkbox"/>		
	Coil/IUD	<input type="checkbox"/>		
	Female sterilisation	<input type="checkbox"/>		
	Male sterilisation	<input type="checkbox"/>		
	Non-effective method	<input type="checkbox"/>		

Have you become PREGNANT again since your abortion (12 months ago)?				
Y	<input type="checkbox"/>	N	<input type="checkbox"/>	

Have you had another ABORTION since your abortion (12 months ago)?				
Y	<input type="checkbox"/>	N	<input type="checkbox"/>	

Contraception calendar data				
Date	Month since abortion	Column 1 Requires a code for every month	Column 2 Code for non-use or if method discontinued	Column 3 Code for every month of initiation of method
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
	11			
	12			

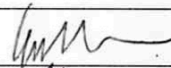

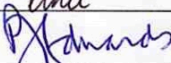
	13			
	14			

Column 1: Contraceptive use, pregnancy, repeat abortion 0. No method 1. Female sterilisation 2. Male sterilisation 3. IUD/coil 4. Injectable 5. Implant 6. Pill 7. Condom 8. Female condom 9. Diaphragm 10. Foam or jelly 11. Lactational amenorrhoea 12. Rhythm method M. Withdrawal X. Other modern method Y. Other traditional method P. Pregnancy A. Abortion	Column 2: Non-use or discontinuation 0. Infrequent sex, husband/partner away 1. Became pregnant whilst using 2. Wanted to become pregnant 3. Husband/partner disapproved 4. Wanted more effective method 5. Side effects/health concerns 6. Lack of access/too far 7. Costs too much 8. Inconvenient to use F. Up to god/fatalistic A. Difficult to get pregnant/menopausal D. Marital dissolution/separation X. Other (specify)	Column 3 codes: 0. MSIC CCA 1. MSIC CTK 2. MSIC CBB 3. MSIC CSR 4. Local market 5. Local pharmacy 6. Friend 7. Other NGO 8. Prefer not to say 9. Other
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STATISTICAL ANALYSIS PLAN

Mobile Technology for Improved Family Planning (MOTIF)

APPROVED BY:

Name	Signature	Date
Principal investigator (1) Chris Smith		16/6/14.
Principal investigator (2) Cari Free		16/6/14
Statistician Phil Edwards		11/6/14

INTRODUCTION

The outline statistical methods for analysis of trial data are set out in the protocol. This document outlines details of the trial and planned analysis and the results that will be presented for four-month and 12-month follow up data from the MOTIF trial (shell tables are in Appendix 1).

STUDY

A randomised controlled trial (RCT) of a mobile phone-based intervention to support post-abortion family planning (PAFP) at four Marie Stopes International (MSI) Cambodia clinics

STUDY OBJECTIVES

To assess the effect of the MOTIF mobile phone-based intervention on PAFP uptake

STUDY DESIGN

MOTIF is a multi-site single blind Randomised Controlled Trial (RCT). Participants are randomised to the mobile phone-based intervention (voice messages and follow-up phone calls) or standard of care (SOC)/control (no additional mobile phone-based support) with a 1:1 allocation ratio.

SAMPLE SIZE

A trial of 500 has 80% power to detect a difference in contraceptive use of 35% vs. 48% (i.e. RR 1.4) at the 5% significance level (i.e. $p < 0.05$)

RANDOMISATION AND BLINDING

The RA provided a written list of all participants recruited, together with a unique trial identification (ID) number, to the counsellor delivering the intervention. The RA sent only the ID number together with the clinic status ('urban' or 'rural') of enrolled participants to a project statistician at LSHTM via email. Participants were stratified according to urban or rural clinic status and allocated to the intervention or control group using a remote computer-based randomisation programme. Allocation was therefore concealed from RAs working on the trial. MOTIF is a behaviour change intervention and therefore it was not possible to blind participants.

FOUR-MONTH FOLLOW UP

1.1 PRIMARY OUTCOME

- Use of an effective modern contraceptive method at four-months post-abortion (self-report) (Yes, No)
 - Effective methods are defined as either oral contraceptive (OC), intra-uterine device (IUD), implant, injectable, or permanent methods.

1.2 SECONDARY OUTCOMES

Secondary outcome measures (all self-report):

At four-months:

- Pregnancy (Yes, No)
- Repeat abortion (Yes, No)
- Effective modern contraception use over four-month period (<80%, >80%)
 - As 12 observations of contraception use were made (one per week) if the participant is using effective contraception for ≥ 10 observations/12 this is considered to fulfil the criteria (10/12=83% the closest approximation to 80%)
- Contraceptive discontinuation (time to failure)

- Discontinuation is defined as stopping effective contraception for one-week or more (in the case of injectable discontinuation is defined as not continuing an effective method 3 months after receiving injection)
- Involvement in any road traffic accidents (RTA) (Yes, No)
- Involvement in any domestic abuse (Yes, No)

In addition to the outcomes outlined in the protocol we will also assess the effect of the intervention on long-acting contraception:

- Long-acting contraception use at four-months post-abortion (implant, IUD, permanent method) (Yes, No)

1.3 ASSESSMENT OF OUTCOMES

The outcome data was collected at four-months. All self-reported outcome variables were recorded on a data collection form and then subsequently on the web-based data entry form.

In order to assess the validity of self-reported data, a reliability study based on 50 participants from participants recruited from the urban clinics near Phnom Penh was conducted. These participants were requested to attend for face-to-face follow-up for objective measurement on all contraception outcomes. This included urine pregnancy testing and measures of contraceptive adherence (presence of sub-dermal implant, clinical examination to identify IUD threads or ultrasound, documentary evidence of injection within the previous three-months, documentary evidence of sterilization, pill counts defined as >90% of pills taken since last prescription dispensed).

2. STUDY POPULATIONS

2.1 PARTICIPANT CHARACTERISTICS

We will create labels for each variable and import the dataset from excel to stata.(2) Once in stata, all actions will be recorded in a 'do file'. We will produce summary statistics to report baseline characteristics of the intervention and control groups, and present as per table 1 in the appendix. A trial profile will be presented as per the CONSORT recommendations.(1)

DEFINITION OF POPULATIONS FOR ANALYSIS

Intention to treat (ITT) principles will be used for primary outcome analysis; therefore all participants' will be analysed according to the arm to which they were randomised, irrespective of whether the patients in the intervention group received the intervention. **The main analysis will include all participants that completed follow up¹.**

2.2 MAJOR PROTOCOL DEVIATIONS

These will be reported in the results section.

2.3 DEFINITION OF SUB-GROUP POPULATIONS

As stated in the protocol, we will undertake exploratory subgroup analysis to assess whether the effect of the intervention varies according to:

- Age (<25, 25 and over)
- Residence (urban, rural)
- Level of education (none or primary, some secondary or above)

¹ The published trial protocol stated that the primary analysis would consider participants lost to follow-up as 'non-users'. This will now be a secondary analysis and the main analysis will include only participants that completed follow up (as per advice given during CS PhD upgrade)

- Socio-economic status (access to motorised transport, no access to motorised transport)

3. STATISTICAL ANALYSIS

3.1 GENERAL

We will report the trial according to the CONSORT standards for reporting RCTs.

Data security

The trial master file, together with completed data collection forms, are kept in a locked filing cabinet at the study co-ordinating centre at the MSIC head office in Phnom Penh. Files will be transferred to LSHTM in September 2014. All electronic data files containing participant identifiable data are password protected. Analysis will be conducted using STATA [2].

3.2 INTERIM ANALYSIS

There will be one analysis of the four-month follow up data after the database has been locked. There will be no interim analyses

3.3 POOLING OF SITES

Data will be pooled across all sources of recruitment

3.4 TIME-POINTS FOR ANALYSIS

For the four-month analysis there will be one analysis at the end of four-month follow-up after the database has been locked

3.5 SECONDARY ANALYSES

Counting those lost to follow up as non-users²

We will conduct an additional sensitivity analysis including all participants. Participants lost to follow-up, resulting in missing contraceptive use outcome data at four-months, will be considered non-users. The primary outcome will be self-reported use of effective contraception. This analysis will be reported in the main paper and the results will be discussed alongside the results of the primary analysis described above.

Per-protocol analysis

Per-protocol analysis will be undertaken to assess the impact of the intervention among those who actively participated in the intervention. Participants who respond (i.e. pressed number '1' or number '2') to three or more of the six voice messages over the intervention period will be considered highly protocol adherent. Participants who respond to between one and three messages will be considered less protocol adherent. Those who never responded to a voice message will be considered as never responding and not included in the sensitivity analysis. These results will be presented in the main paper.

Clustering among participants from one clinic

We will conduct analysis to assess the impact of the intervention according to clinic (CBB, CSR, CCA, CTK) and report RR and 95% confidence interval for the primary outcome

3.6 STATISTICAL ANALYTICAL ISSUES

There will be one analysis at the end of the trial after the database has been locked

3.6.1 ADJUSTMENTS FOR COVARIATE

There will be no covariate adjustment in the primary analysis

² As per footnote 1: counting those lost to follow-up as non-users was originally the primary analysis and has now been changed to a secondary analysis

3.6.2 MULTIPLE COMPARISONS

There will be no adjustment for multiple comparisons. We will report 99% confidence intervals for subgroup analysis of the primary outcome

3.6.3 EXAMINATION OF SUBGROUPS

The study is powered for the primary outcome. Recognising that the study has limited power and that any inferences would be tentative we will undertake exploratory sub-group analyses to assess evidence for whether the effect of the intervention varies according to age, urban versus rural residence, level of education, and socioeconomic status. We will use the **chi-squared test for heterogeneity** at a 5% level of significance. If statistically significant overall heterogeneity is identified then relative risks and 99% confidence intervals will be estimated.

4. EVALUATION OF DEMOGRAPHIC AND BASELINE CHARACTERISTICS

As outlined above, a trial profile will be presented as per the CONSORT recommendations (fig 1). The baseline characteristics will be presented according to intervention (table 1).

5. EVALUATION OF COMPLIANCE TO INTERVENTION

The number of participants that opted out of receiving the intervention will be reported in the results section.

6. EVALUATION OF PARAMETERS

6.1 ANALYSIS OF PRIMARY, SECONDARY, AND OTHER ENDPOINTS

The primary outcome measure is use of an effective modern contraceptive method at four months. Participants will be considered to meet the criteria for 'use' of effective modern contraception according to method:

- implant (participant currently has a sub-dermal implant); IUD (participant currently has IUD inserted)
- injectable (client has received injection within the previous three months)
- permanent method (client, or husband/partner has had sterilisation or vasectomy procedure)
- OC (participant reports having taken pill within 24 h of interview or, if on seven-day break, took the last pill according to instructions).

We will calculate the sensitivity and specificity of self-reported contraception use as compared to objective measurement, and comment on any limitations of the respective methods of data collection.

6.2 METHOD FOR ANALYSIS OF ENDPOINTS

6.2.1 BINARY DATA

For the primary outcome and secondary outcomes with binary outcome measures we will estimate risk ratios with 95% confidence intervals and give a two-sided p-value for statistical significance using chi-squared test. For subgroup analysis (primary outcome only) we will report relative risks with 99% confidence intervals with two-sided p-value.

6.2.2 COUNT DATA

Not applicable

6.2.3 TIME-TO-EVENT DATA

We will undertake Kaplan Meier survival analysis to assess discontinuation rates as follows:

- Data on contraceptive use per week was collected at follow up. For each week (1-12) contraceptive use according to method, non-use, pregnancy, or repeat abortion was recorded
- The analysis of discontinuation will only include participants who started using an effective method of contraception during weeks 1-4
- Discontinuation is defined as stopping effective contraception for one-week or more (in the case of injectable discontinuation is defined as not continuing an effective method 3 months after receiving injection)
- If the participant switches from one effective method to another with no break this is not considered discontinuation
- We will use the Mantel-Cox X^2 (log rank) test to compare discontinuation rates between intervention and control groups and present the log rank X^2 statistic and p-value

7. EVALUATION OF SAFETY PARAMETERS

7.1 ADVERSE EVENTS

Involvement in RTA or domestic violence are the only plausible adverse events that might be caused by a mobile phone-based voice message intervention. These will be recorded as secondary outcomes.

12-MONTH FOLLOW UP

12-month follow up will be conducted on all 500 trial participants apart from 8 that withdrew from the study at four-months. Outcome measures and analysis will be similar to four-month data with the following differences *in italics*:

11. PRIMARY OUTCOME

- Use of an effective modern contraceptive method at *12-months* post-abortion (self-report) (Yes, No)

11.1 SECONDARY OUTCOMES

At *12-months*:

- Pregnancy (Yes, No)
- Repeat abortion (Yes, No)
- Effective modern contraception use over *12-month* period (<80%, >80%)
 - 12 observations of contraception will be made (one per *month*) if the participant is using effective contraception for ≥ 10 observations/12 this is considered to fulfil the criteria (10/12=83% the closest approximation to 80%)
- Contraceptive discontinuation (time to failure)
 - Discontinuation is defined as stopping effective contraception for *one-month* or more (in the case of injectable discontinuation is defined as not continuing an effective method 3-months after receiving injection)
 - This analysis will include all participants that initiated effective method *during the first 3 months post-abortion* (i.e. the duration of the intervention. The hypothesis being that starting PAFP during intervention period resulted in better counselling and less likelihood of discontinuation)
 - This analysis will only apply to the first time a participant started an effective method i.e. will include just single failure not multiple failures

N.B: Research assistants conducting 12-month follow up will be blinded to treatment allocation and will not be aware of data collected at four-months. In the event of discrepancy between four-month and 12-month data, we will use the four-month data for the analysis as this will be less prone to recall

bias. We will report on the degree of discrepancy between the four-month data and data collected at 12-months.

In addition to the outcomes outlined in the protocol we will also assess the effect of the intervention on long-acting contraception:

- Long-acting contraception use at 12-months post-abortion (implant, IUD, permanent method) (Yes, No)

12. SENSITIVITY AND SUB-GROUP ANALYSIS

As per four-month data

References

1. CONSORT 2010 checklist of information to include when reporting a randomised trial [Internet]. 2010. p. 1-2. Available from: <http://www.consort-statement.org/>
2. StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP.

APPENDIX 1: SHELL TABLES

Figure 1 Flow chart

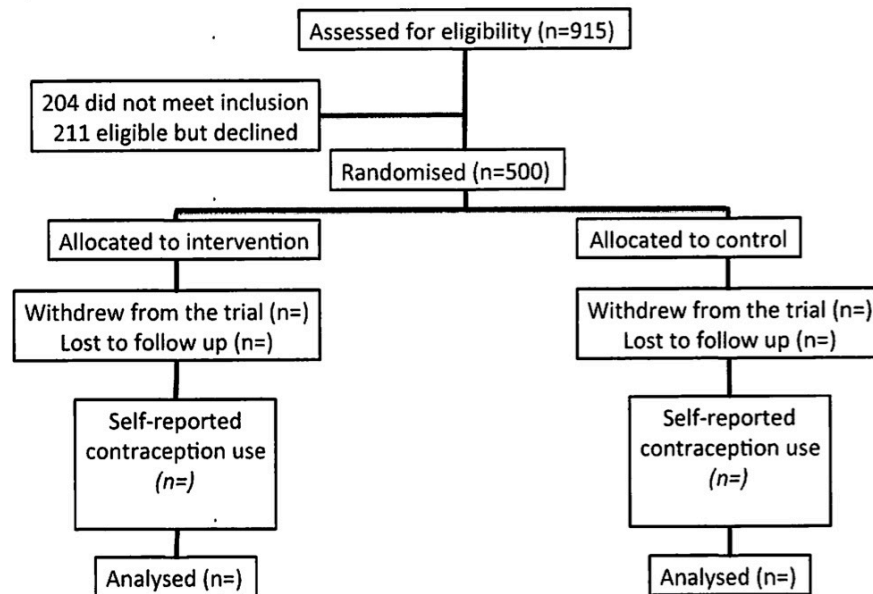


Table 1 Baseline data

	Intervention group (n=)	Control group (n=)
Age		
	<25	
	25 or more	
Residence status		
	Rural	
	Urban	
Education		
	None/primary	
	Secondary or above	
Socioeconomic status		
	Access to motorised transport	
	No access to motorised transport	
Marital status		
	Married/living together	
	Never married or living together	
	Divorced/separated	
Literacy		
	Able to recognize numbers	
	Not able to recognize numbers	
Number of living children		
	0	
	1-2	
	3 or more	

Previous abortions
0
1
2 or more
Type of abortion
Medical
Surgical
PAFP intention at time of randomisation
Yes
No
Undecided
Mobile phone access
Shares
Never shares

Table 2: Primary and secondary outcomes at four-months

	Intervention group (number [%])	Control group (number [%])	RR (95% CI)	P value
Primary outcome				
Self-reported use of effective PAFP				
Secondary outcomes				
Total attrition (missing)				
Loss to follow-up				
Withdrawal				
Pregnancy				
Repeat abortion				
Contraception use over 4-month period				
Involvement in RTA ³				
Domestic abuse				
Contraceptive discontinuation				

Data are percentage or relative risk (95% CI), hazard ratio for discontinuation

Figure 2: Effect of intervention on primary outcome by subgroup⁴

	Intervention	Control	Subgroup RR (99% CI)*
Age			
<25			
>=25			
Residence			
Rural			
Urban			
Socioeconomic status			
Access to motorised transport			
No access to motorised transport			
Level of education			
None or primary			
Some secondary or above			
Overall**			
			< Control better Intervention better >
*99% CI for RR by subgroups **95% CI for overall RR			

³ For 12-month follow up the table will be the same except that it won't include Involvement in RTA or domestic abuse as these data were only collected at four-months as a potential adverse outcome during the intervention delivery i.e. first three months

⁴ We will only report findings from subgroup analysis if statistically significant overall heterogeneity is identified

Appendix 5: Evidence of permission to include published work

Cochrane review (Chapter 2)

Date: 4 October 2016, 16:36

Dear Frans – I have spoken to David and the answer is that if Chris is the main author of the Review, he can include it in his PhD thesis. He would require further permission if he wants to publish elsewhere.

I hope that is ok? Please do email again if you need further clarification.

Bw, Hilary

Hilary Simmonds

PA to David Tovey, Editor in Chief and Deputy Chief Executive Officer

Cochrane Central Executive

Intervention development (Chapter 3)

Date: 7 October 2016, 09:36

Dear Chris,

Thank you for your email,

Please note you are able to include articles within text as long as it has been correctly cited and referred to BMC

Thank you

Krishika

Miss Krishika Dogra

Production Editor

BioMed Central

Trial protocol (Chapter 4)

Date: 6 October 2016, 11:04

Dear Dr Smith,

Thank you for your email. As long as you cite the journal correctly, then we have no problem with you including it in your thesis.

Best wishes,

Rebecca Kirk

Editorial Office Manager

BioMed Central

Floor 6, 236 Gray's Inn Road
London

WC1X 8HB

Trial results (Chapter 5)

Dear Dr Smith,

Thank you for your message. Under the Creative Commons attribution 3.0 IGO licence, you are permitted to share and redistribute the material on the condition that you cite the original Bulletin source. Please see the following link for information on the CC 3.0 IGO CC BY licence:

<https://creativecommons.org/licenses/by/3.0/igo/>

Kind regards,

Kaylene Selleck

Editorial Assistant

the Bulletin of the World Health Organization

Appendix 6: Counselling guide

A. Introduction

'This is a phone call from Marie Stopes counsellor. Please can you tell me your name and age?'
'Is this a convenient time for you to talk?' If NO, arrange another time to call client

B. Seek information from client

'The purpose of the phone call is for me to provide support regarding contraception. To start with I would like to ask you some questions.'
'What was the reason that you pressed '1' OR 'What was the reason that you didn't respond to the voice message?'

C. Provide counselling advice

'Are you currently using a method of contraception?'

Coil (1)	<input type="checkbox"/>	<i>'It is good that you are using such an effective and safe method of contraception to avoid becoming pregnant at this time'</i>
Implant (2)	<input type="checkbox"/>	
Injection (3)	<input type="checkbox"/>	<i>'Do you have any questions about the method you are using / any side-effects?'</i> <ul style="list-style-type: none"> • Provide appropriate advice on side-effects [see additional information in the Counsellor Standard Operating Procedure handbook] • If using injection, offer injection reminder
Pill (4)	<input type="checkbox"/>	<i>'Do you use the pill every day / are you comfortable/fine with the pill / any side-effects?'</i> <ul style="list-style-type: none"> • Provide appropriate advice on side-effects • Remind client pill only effective if taken every day at same time • Offer pill reminder <i>'Would you like some information about other effective long-acting contraception methods?'</i> (SEE BELOW)
Condom (5)	<input type="checkbox"/>	<i>'Condom is good for STI/HIV prevention' 'Does your partner use condoms every time you have intercourse?'</i> <ul style="list-style-type: none"> • Remind client condom only effective if used correctly every time <i>'Would you like some information about other effective long-acting contraception methods?'</i> (SEE BELOW)
Calendar (6)	<input type="checkbox"/>	<i>'This is not an effective method to prevent pregnancy. You are at risk of becoming pregnant again'</i>
Withdrawal (7)	<input type="checkbox"/>	<i>'Would you like some information about other effective long-acting contraception methods?'</i> (SEE BELOW)
Permanent (8)	<input type="checkbox"/>	Ask client if they still require voice messages
Other (9)	<input type="checkbox"/>	Please state:
No method (10)	<input type="checkbox"/>	<i>'Is there any reason why you are not using a method?'</i> <ul style="list-style-type: none"> • Give same advice as for calendar/withdrawal

Reason for non use	Counselling and advice
Want to become pregnant (1)	Advice avoid pregnancy for 6 months
Abstain (2)	Ask reason. <i>'When do you think you will need contraception again?'</i>
Husband/partner disapprove (3)	Ask reason e.g. Uncomfortable with coil / afraid of infertility <i>'Would you like me to discuss with your husband?'</i>
Cost (4)	Explain cost of injection / IUD cheap (especially compared to abortion) also cheap per year

- Distance (5)** Long-acting methods: one visit protects for many years
Local provider e.g. injection from health centre/private clinic
- Side effects/health concerns (6)** Depend on method
Reassure, refer to clinic or suggest other long-acting methods
- Lack of knowledge (7)** Give information on methods
- Other (8)** Please state:

Information about long-acting methods

*"Here are some advantages of the long-acting methods (such as **coil, implant, injection, permanent**):*

- They are the most **effective** methods to prevent unplanned pregnancy
- **Safer** for your health & **cheaper** for you rather than have repeat abortion
- They do not effect your **future fertility**
- You **don't have to remember to take it every day**"

Method	Advantages	Availability
Coil	Protects for 10 years, no hormone, normal period	MSI clinic > MSI partner clinic
Implant	Protects 3-5 years, good for ladies any age	
Injection	Protects for 3 months, one hormone, secret	MSI clinic, HC
Permanent (vasectomy/sterilisation)	Free, never need contraception, good if completed family	Some MSI clinics*

D. Outcome of phone call

'So what do you plan to do for contraception?'

- Client will same **continue** method (1) ☐
- Client will **start new method**(2) ☐
- Client will **change** method (3) ☐ Name of new method:
- Client will **stop** using current method (4) ☐
- Client plans to continue **not using** a method (5) ☐

'I would like to confirm what I have arranged for you'

- Pill or injection **reminder** (1) ☐ Date:
- Refer to clinic for **check up** (2) ☐ Clinic:
- Appointment made** at clinic (3) ☐ Clinic: Date:
- Additional follow up **phone call**(4) ☐ Date:
- Cancel future voice messages/opt out** (5) ☐

Advice given to **someone other than client** ☐ Who?:

'You will receive another voice message in two weeks time and you can press '1' to request a call from a counsellor or '2' if you are fine. If you need to speak to a counsellor before then you can call the MOTIF service'